IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

BIONTECH SE, BIONTECH MANUFACTURING GMBH, and PFIZER INC.,	)	
Plaintiffs/Counterclaim Defendants,	)	C.A. No. 2:23cv222-EWH-DEM
v.	)	**JURY TRIAL DEMANDED**
CUREVAC SE and CUREVAC MANUFACTURING GMBH,	)	
Defendants/Counterclaim Plaintiffs.	)	

CUREVAC SE'S COUNTERCLAIMS AND ANSWER

COUNTERCLAIMS

Defendants-Counterclaim Plaintiffs CureVac SE and CureVac Manufacturing GmbH (collectively "CureVac") hereby allege for their Counterclaims against Plaintiffs-Counterclaim Defendants BioNTech SE and BioNTech Manufacturing GmbH ("BioNTech Manufacturing") (collectively "BioNTech") and Pfizer Inc. ("Pfizer"):

CUREVAC'S PIONEERING WORK ON mRNA MEDICINES

1. CureVac was the pioneer in the development of a completely new class of medicines based on messenger RNA (mRNA). These medicines use the mRNA molecule as a carrier of information to allow the body to produce its own active substances to treat or prevent disease. Although many doubted that this technology could ever be used to treat or prevent disease, CureVac recognized very early that it had great potential to improve patients' lives. Since CureVac's founding in 2000 in Tübingen, Germany, CureVac has been singularly focused on making mRNA medicines a reality through substantial investment and more than two decades of research and development.

2. As a molecule found within all forms of cellular life, mRNA is central to biology: it is literally the "messenger" between DNA, the body's genetic blueprint, and proteins, the molecules responsible for the structure, function, and regulation of essentially all processes in the body. For many years after its discovery, mRNA was considered too unstable to be used therapeutically (mRNA is quickly destroyed both outside and inside the body), and was therefore relegated into the shadow of its much more stable sister molecule, DNA. But in the late 1990s, CureVac's founder, Dr. Ingmar Hoerr (although only a graduate student at the time), made a completely unexpected discovery: despite being unstable, mRNA could be directly administered to animals, without complicated reformulations or molecular packaging, where it could cause cells to produce the protein encoded by the mRNA.

3. With this ground-breaking discovery, in 2000, Dr. Hoerr and others founded CureVac and began to challenge the status quo by developing this unproven technology to treat and prevent some of the deadliest diseases and medical conditions, including cancer. Despite other companies' current claims to be the "pioneers" in this field, CureVac was the first company in the world to harness mRNA for medical purposes—because the CureVac scientists saw opportunities where others saw only obstacles.

4. Convinced that mRNA has unparalleled potential as a medicine, CureVac's scientists have worked diligently in its laboratories to pioneer numerous fundamental breakthroughs in the field of mRNA technology. These discoveries span all aspects of mRNA medicines, including methods to stabilize mRNA, to modify it, to manufacture it on a commercial scale, to increase the yield of the protein it encodes, and to formulate it for safe and effective administration to patients.

5. Based on that research, CureVac is developing medicines to treat and prevent a wide range of diseases—infectious diseases like COVID-19 and influenza, liver and eye diseases, and particularly treatment-resistant cancers.

6. All told, CureVac and its 1000 employees invested many thousands of hours and more than a billion dollars to develop an mRNA medicines platform that could be applied across a variety of therapeutic and prophylactic (*e.g.*, vaccine) applications.

PARTIES

7. CureVac SE is a corporation organized and existing under the laws of Germany, having a place of business at Friedrich-Miescher-Straße 15, 72076 Tübingen, Germany. In September 2022, CureVac AG was merged with CureVac Beteiligungsverwaltungs AG (registered office in Vienna, Austria). As part of that merger, CureVac AG changed its name to CureVac SE, which on September 26, 2022, was registered in the Stuttgart commercial register.

8. CureVac Manufacturing GmbH is a corporation organized and existing under the laws of Germany, having a place of business at Friedrich-Miescher-Straße 15, 72076 Tübingen, Germany. CureVac Manufacturing GmbH is a wholly-owned subsidiary of CureVac N.V.

9. CureVac SE and CureVac Manufacturing GmbH are the owners by assignment of the patents asserted in this litigation.

10. On information and belief, Pfizer is a corporation organized and existing under the laws of Delaware, with its principal place of business at 235 East 42nd Street, New York, NY 10017.

11. On information and belief, BioNTech SE is a corporation organized and existing under the laws of Germany, with its principal place of business at An der Goldgrube 12, Mainz, 55131 Germany.

12. On information and belief, BioNTech Manufacturing, a wholly-owned subsidiary of BioNTech SE, is a limited liability company organized and existing under the laws of Germany, with its principal place of business at An der Goldgrube 12, Mainz, 55131 Germany.

13. On information and belief, BioNTech Manufacturing is the Biologics License Application ("BLA") holder for Comirnaty® in the United States.

14. On information and belief, Pfizer and BioNTech jointly developed and commercialized Comirnaty®.

JURISDICTION AND VENUE

15. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, et seq. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1367(a).

16. Personal jurisdiction is proper in this Court over Pfizer and BioNTech at least because, on information and belief, Pfizer and BioNTech engaged in infringing acts in this District.

17. Pfizer and BioNTech have consented to venue in this Court by filing their declaratory judgment complaint, which was transferred to this Court, and venue is proper pursuant to 28 U.S.C. §§ 1391(b)–(c).

CUREVAC'S PATENTS

18. The use of mRNA as a vaccine has long been hampered by, for example, its instability, the difficulty in getting it inside the target cells in the body, its inability to produce sufficient quantities of the desired protein once it is inside those cells, the insufficient stimulation of the immune system by the expressed protein, and various undesirable side effects (called "reactogenicity"). In its more than two decades of developing mRNA technologies, CureVac encountered and developed solutions to these many technical challenges presented by this entirely new way to treat and prevent disease. CureVac has sought to protect its substantial investment in

research and development in the field of mRNA medicines by obtaining patents that cover its inventions.

19. To overcome the instability of mRNA so that it could be used in vaccines and other medicines, CureVac's scientists had to develop novel ways to stabilize it by modifying its structure. mRNA typically is composed of four different nucleosides: adenosine, guanosine, cytidine, and uridine. The sequence of these nucleosides in an mRNA molecule provides instructions that cells use to create the particular protein it encodes. CureVac's scientists discovered that increasing the proportions of guanosine and cytidine nucleosides in an mRNA stabilizes the molecule and results in an increased expression of the protein it encodes. In 2001, CureVac filed its first patent application directed to this advance in mRNA technology.

20. On October 5, 2021, the U.S. Patent & Trademark Office issued U.S. Patent No. 11,135,312 ("the '312 patent") titled "Pharmaceutical Composition Containing a Stabilised mRNA Optimised for Translation in its Coding Regions." The '312 patent names CureVac's co-founders, Florian Von der Mülbe, Ingmar Hoerr, and Steve Pascolo, as inventors. A true and correct copy of the '312 patent is attached as Exhibit 1.

21. The levels at which an mRNA expresses the protein it encodes is of primary importance to the development of an mRNA vaccine. An mRNA has discrete parts: the part that is translated to make a protein inside a cell, and the other, untranslated, parts that facilitate the translation. CureVac scientists discovered that modifying one of those untranslated regions, composed of sequential adenosine nucleotides at one end of the mRNA (often called "polyA"), results in a substantial increase in the amount of protein expressed by the cell or organism. In 2014, CureVac filed its first patent application directed to this advance in mRNA technology. On October 19, 2021, the U.S. Patent & Trademark Office issued U.S. Patent No. 11,149,278 ("the '278

patent") titled "Artificial nucleic acid molecules for improved protein expression." A true and correct copy of the '278 patent is attached as Exhibit 2. On March 29, 2022, the U.S. Patent & Trademark Office issued U.S. Patent No. 11,286,492 ("the '492 patent") titled "Artificial nucleic acid molecules for improved protein expression." A true and correct copy of the '492 patent is attached as Exhibit 3. On May 31, 2022, the U.S. Patent & Trademark Office issued U.S. Patent No. 11,345,920 ("the '920 patent") titled "Artificial nucleic acid molecules for improved protein expression." A true and correct copy of the '920 patent is attached as Exhibit 4. The '278, '492, and '920 patents list Andreas Thess, Thomas Schlake, and Stefanie Grund as inventors.

22. The development of mRNA into a viable alternative to traditional drug products required the development of a commercially viable, efficient, and effective method of producing and purifying mass quantities of mRNA. To enable a sufficient supply of mRNA for use as a therapeutic, CureVac's scientists developed new methods to purify the mRNA, as well as the DNA template which encodes the mRNA, using a technique called Tangential Flow Filtration ("TFF"). In 2015, CureVac filed its first patent application directed to this advance in mRNA technology.

23. On September 1, 2020, the U.S. Patent & Trademark Office issued U.S. Patent No. 10,760,070 ("the '070 patent") titled "Method for producing and purifying RNA, comprising at least one step of tangential flow filtration." A true and correct copy of the '070 patent is attached as Exhibit 5. The '070 patent lists Andreas Funkner, Stefanie Dorner, Stefanie Sewing, Johannes Kamm, Norbert Broghammer, Thomas Ketterer, and Thorsten Mutzke as inventors.

24. Following Dr. Hoerr's groundbreaking discovery in 1999 that "naked" mRNA could generate an immune response in an organism, CureVac scientists spent two decades conducting foundational research to develop methods of delivering mRNA into cells to safely maximize the immune response. In 2014, working with its partners, CureVac began an extensive

program to improve the delivery system for its mRNA medicines. That program resulted in the selection of a "lipid nanoparticle" ("LNP") containing an mRNA complexed with an ionizable cationic lipid; distearoylphosphatidylcholine; cholesterol; and a polyethylene glycol-appended lipid. The selection of that delivery mechanism from amongst all those tested by CureVac was validated in a first-in-humans Phase I clinical trial of an mRNA vaccine against rabies.

25. When the COVID-19 pandemic struck, CureVac scientists leveraged their resources and expertise to find the optimal mRNA sequence encoding the full-length COVID-19 spike protein, and packaged that mRNA in the LNP that resulted from CureVac's selection and validation process in the human rabies vaccine trial. In 2020, CureVac filed its first patent application directed to this advance in mRNA technology.

26. On February 8, 2022, the U.S. Patent & Trademark Office issued U.S. Patent No. 11,241,493 ("the '493 patent") titled "Coronavirus vaccine." A true and correct copy of the '493 patent is attached as Exhibit 6. On October 18, 2022, the U.S. Patent & Trademark Office issued U.S. Patent No. 11,471,525 ("the '525 patent") titled "Coronavirus vaccine." A true and correct copy of the '493 patent is attached as Exhibit 7. On February 14, 2023, the U.S. Patent & Trademark Office issued U.S. Patent No. 11,576,966 ("the '966 patent") titled "Coronavirus vaccine." A true and correct copy of the '966 patent is attached as Exhibit 8. On March 7, 2023, the U.S. Patent & Trademark Office issued U.S. Patent No. 11,596,686 ("the '686 patent") titled "Coronavirus vaccine." On March 7, 2023, the U.S. Patent & Trademark Office issued U.S. Patent No. 11,596,686 ("the '686 patent") titled "Coronavirus vaccine." A true and correct copy of the '686 patent is attached as Exhibit 9. The '493, '525, '966, and '686 patents list Susanne Rauch, Hans Wolfgang Grosse, and Benjamin Petsch as inventors. On March 24, 2023, CureVac petitioned the U.S. Patent & Trademark Office to correct the '493 and '525 patents by adding

Mariola Fotin-Mleczek, Patrick Baumhof, and Regina Heidenreich as inventors. True and correct copies of the petitions are attached as Exhibit 10 and Exhibit 11.

27. CureVac SE owns the '312, '278, '492, '920, '493, '525, '966, and '686 patents. CureVac Manufacturing GmbH owns the '070 patent.

COMIRNATY®

28. On information and belief, prior to the emergence of COVID-19, Pfizer and BioNTech had begun researching an mRNA vaccine for influenza, but lacked expertise in developing mRNA vaccines for coronaviruses and other infectious diseases. Indeed, BioNTech's CEO, Uğur Şahin, was reported to have said that infectious disease targets were "not a priority" for his company before COVID-19.

29. According to news reports, Pfizer apparently lacked any mRNA candidates in clinical trials before COVID-19, and BioNTech did not have any such candidates in clinical trials for infectious diseases. Although Pfizer and BioNTech started their development of an mRNA vaccine for COVID-19 after such programs began at other companies, they quickly made-up ground by utilizing CureVac's patented inventions, albeit without a license from CureVac to do so.

30. Pfizer and BioNTech had many choices for how they could design their COVID-19 vaccine. Indeed, on information and belief, Pfizer and BioNTech's COVID-19 vaccine program—"Project Lightspeed"—started with more than twenty vaccine candidates representing different mRNA constructs and target antigens that BioNTech took into preclinical testing. As they got further along in their clinical development, they ultimately focused exclusively on vaccine designs that used CureVac's patented technologies. By April 23, 2020, they had narrowed their effort to four candidates.

31. On July 27, 2020, Pfizer and BioNTech announced they had chosen to advance a single COVID-19 vaccine candidate called "BNT162b2" to a Phase II/III clinical trial. On information and belief, BNT162b2 is for all relevant purposes identical to the Comirnaty® product.

32. On information and belief, on August 23, 2021, BioNTech received approval to market Comirnaty® (tozinameran) in the United States. According to the Comirnaty® package insert, "Comirnaty is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)." Exhibit 12 (Comirnaty® package insert) at 1; Exhibit 13 (Comirnaty® Bivalent package insert) at 16. The active ingredient in Comirnaty® is tozinameran, an mRNA that encodes the viral spike glycoprotein on SARS-CoV-2 (and in later versions, Comirnaty® also contains famtozinameran, an mRNA that encodes the viral spike glycoprotein on the Omicron BA.4-5 variants of SARS-CoV-2). Exhibit 12 (Comirnaty® package insert) at 14; Exhibit 13 (Comirnaty® Bivalent package insert) at 16. Tozinameran (and famtozinameran) contains five elements: (1) a modified 5' cap (a chemically modified form of the nucleotide guanosine triphosphate); (2) a 5' untranslated region (a leader sequence); (3) an S glycoprotein signal peptide (an extended leader sequence); (4) a "codon-optimized sequence" encoding the full-length SARS-CoV-2 spike (S) glycoprotein containing mutations modifying two positions so that they are translated to incorporate prolines; and (5) a 3' untranslated region that includes a "110-nucleotide poly(A)-tail consisting of a stretch of 30 adenosine residues, followed by a 10-nucleotide linker sequence and another 70 adenosine residues." Exhibit 14 (WHO INN Programme Report No. 11889) at 1-2; Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("A30L70 (nucleotides 4159 to 4268)"). When tozinameran and famtozinameran are transcribed from their respective plasmids, a modified form of uridine, 1-methyl-3'-pseudouridylyl, is incorporated at the positions that would otherwise

contain uridine residues. Exhibit 14 (WHO INN Programme Report No. 11889) at 2-4; Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 3.

33. Pfizer and BioNTech's strategy of using CureVac's inventions was very successful. On November 18, 2020, Pfizer and BioNTech announced that BNT162b2 showed 95% efficacy against the original coronavirus strain in study participants who had no prior SARS-CoV-2 infection. On December 11, 2020, the FDA granted an Emergency Use Authorization ("EUA") for the use of BNT162b2 in individuals over 16 years of age. On August 23, 2021, the FDA approved the BLA for Comirnaty® (BNT162b2) for use in individuals over 16 years of age.[1] On October 29, 2021, the FDA authorized the use of Pfizer and BioNTech's COVID-19 vaccine in children between 5 and 11 years of age pursuant to an EUA. On September 22, 2021, the FDA amended the EUA for Comirnaty® to permit administration of a booster dose in certain individuals six months after completing their primary two-dose series with Comirnaty®. On November 19, 2021, the FDA expanded the EUA to permit a booster dose of Comirnaty® for individuals who are at least 18 years old and allowed for the administration of a Comirnaty® booster in individuals who completed their primary vaccination series with any FDA-authorized or approved COVID-19 vaccine. The FDA further expanded the EUA to permit a booster dose of Comirnaty® in 16- and 17-year-olds on December 9, 2021, and for individuals 12-years-old or older on January 3, 2022. On January 3, 2022, the FDA also shortened the time period for administration of the third booster dose of Comirnaty® to five months after completion of the primary vaccination series. On March 29, 2022, the FDA authorized individuals who are over the age of 50 or immunocompromised patients who are 12 years old or older to receive a second booster dose of Comirnaty® four months

[1] "Comirnaty®" as used herein includes Pfizer and BioNTech's COVID-19 vaccine made and sold both before and after approval of the BLA therefor, and expressly includes all products made, sold, and used under any and all Emergency Use Authorizations.

after receiving a first booster dose. On May 17, 2022, the FDA expanded the use of Comirnaty® as a single booster dose for administration to individuals 5 through 11 years of age at least five months after completion of a primary vaccination series. On June 17, 2022, the FDA expanded the EUA for Pfizer and BioNTech's vaccine to include the use of the vaccine in individuals between six months and 4 years of age. On August 31, 2022, the FDA amended the EUA to authorize bivalent formulations of Comirnaty® for use as a single booster dose at least two months following primary or booster vaccination. On December 8, 2022, the FDA amended the EUA to authorize bivalent formulations of Comirnaty® for use as a single booster dose in children down to 6 months of age. On March 14, 2023, the FDA amended the EUA to authorize bivalent formulations of Comirnaty® for use in children six months through four years of age at least two months after completion of primary vaccination series with three doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine. On April 18, 2023, the FDA amended the EUA to authorize bivalent formulations of Comirnaty® to be used for all doses administered to individuals 6 months of age and older, including for an additional dose or doses for certain populations. As of April 18, 2023, the monovalent Pfizer-BioNTech COVID-19 vaccine is no longer authorized for use in the United States.

34. Pfizer and BioNTech have enjoyed a financial windfall from their use of CureVac's patented technologies. To date, Pfizer and BioNTech have provided over 591 million doses of their COVID-19 vaccine for use in the United States. *See* https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total (available in archival form at https://perma.cc/2Y4U-KPSU). Pfizer reported that the COVID-19 vaccine generated $36.7 billion in revenue in 2021, $7.8 billion of which resulted from U.S. sales. *See* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-reports-fourth-quarter-

and-full-year-2021-results at 35 (available in archival form at https://perma.cc/87HM-CLFW). Pfizer recently reported that the COVID-19 vaccine generated $37.806 billion in revenue in 2022, $8.775 billion of which resulted from U.S. sales. *See* https://s28.q4cdn.com/781576035/files/doc_financials/2022/q4/Pfizer-10-K.pdf at 38 (available in archival form at https://perma.cc/93VM-QA4D). In 2021, BioNTech reported €18.874 billion in revenue, of which €15.5 billion was recognized from Pfizer related to the COVID-19 vaccine, of which €14.636 billion was recognized revenues in the United States. https://investors.biontech.de/static-files/a159ee32-cca9-4cea-8460-67dfaa289c39 at 141 (available in archival form at https://perma.cc/43Y2-8W7K). In 2022, BioNTech reported €17.194 billion in revenue, of which €13.79 billion was recognized from Pfizer related to the COVID-19 vaccine, of which €12.709 billion was recognized revenues in the United States. *See* https://investors.biontech.de/static-files/4e7e11ad-14dd-4b8b-9ad8-5500c6681b4a at 141 (available in archival form at https://perma.cc/SPR2-AUAV).

35. Pfizer and BioNTech have made clear that they intend to continue to reap profits from their use of CureVac's patented technologies, including by making product in the United States to serve the global market. For example, in December 2021, the Committee for Medicinal Products for Human Use of the European Medicines Agency approved Pfizer and BioNTech's request to scale up production at Pfizer's facility in Andover, Massachusetts "to support the continued supply of Comirnaty in the European Union."

36. Pfizer and BioNTech have also made clear that they intend to sell additional booster doses of Comirnaty®. For example, on March 29, 2022, the FDA authorized certain people to receive a second booster dose of Pfizer and BioNTech's COVID-19 vaccine. Pfizer and BioNTech actively promote the use of booster doses for their COVID-19 vaccine, including through their

website for Comirnaty®: https://www.comirnaty.com/booster-dose/ (available in archival form at https://perma.cc/7WHG-LZ3B).

37. All Comirnaty® made and administered in the United States was distributed by Pfizer to hospitals, pharmacies, clinics, and numerous other entities for the benefit of individual vaccine recipients in the United States. *See* https://cdn.pfizer.com/pfizercom/Pfizer_PGS_COVID-19_Factsheet_071122.pdf. All Comirnaty® administered in the United States was manufactured in the United States. *Id.*

38. In recognition of the need for ensuring access to the accused vaccines, CureVac is not seeking the removal of Comirnaty® from the market or to prevent its future sale. CureVac brings these counterclaims for patent infringement so that it may obtain fair compensation for Pfizer and BioNTech's past and continued use of CureVac's patented technologies. That fair compensation will translate into an opportunity for CureVac to reinvest in its leading mRNA platform.

COUNT I – INFRINGEMENT OF THE '312 PATENT

39. CureVac incorporates each of the above paragraphs 1–38 as though fully set forth herein.

40. The '312 patent is directed to methods for stabilizing mRNA molecules by altering the coding sequence. The '312 patent inventors discovered that increasing the content of guanine and cytosine residues ("the G/C content") in the coding sequence of an mRNA increases its stability and allows for increased polypeptide production from the mRNA.

41. The '312 patent issued with sixteen claims. Claim 1, the only independent claim, recites:

> **1.** A method for producing a stabilized mRNA molecule encoding a polypeptide, wherein the stabilized mRNA molecule encoding the polypeptide comprises a coding sequence that has an increased Guanine/Cytosine (G/C) content relative to

the original coding sequence encoding the polypeptide, said relative G/C content being increased by at least 7 percentage points compared to the original coding sequence encoding the polypeptide, to thereby produce a stabilized mRNA molecule, wherein said increase in relative G/C content results in the elimination of at least one destabilizing sequence element (DSE), wherein the stabilized mRNA molecule Exhibits enhanced expression of the polypeptide compared to mRNA having the original coding sequence encoding the polypeptide.

42. Dependent claims 7–9 serially narrow claim 1:

7. The method of claim 1, wherein synthesizing the stabilized mRNA comprises producing a DNA molecule encoding the stabilized mRNA.

8. The method of claim 7, wherein synthesizing the stabilized mRNA further comprises transcribing the stabilized mRNA from the DNA molecule.

9. The method of claim 8, wherein the transcription is in vitro transcription.

43. Claim 14 depends from claim 1, and recites:

14. The method of claim 1, further comprising the formulating the stabilized mRNA into a pharmaceutically acceptable carrier.

44. Claim 15 depends from claim 1, and recites:

15. The method of claim 1, further comprising synthesizing a stabilized mRNA comprising at least one nucleotide position replaced with a nucleotide analogue.

45. On information and belief, the method Pfizer and BioNTech (the "Counterclaim Defendants") have used and continue to use to manufacture Comirnaty® satisfies each and every element of at least claims 1, 7–9, 14, and 15 in the '312 patent. Counterclaim Defendants' actions with respect to Comirnaty® have thus infringed at least these claims in the '312 patent.

46. On information and belief, the coding sequence of the tozinameran (and famtozinameran) in Comirnaty® has a G/C content that is increased by about 19 percentage points compared to the original coding sequence encoding the spike glycoprotein on SARS-CoV-2, and is (1) more stable (*i.e.*, indicating that at least one destabilizing sequence element has been eliminated) and (2) provides enhanced expression of the spike glycoprotein as compared to the

original coding sequence. Counterclaim Defendants' manufacture of Comirnaty® therefore infringes claim 1 of the '312 patent.

47. On information and belief, the tozinameran (and famtozinameran) in Comirnaty® is synthesized by producing a template DNA molecule encoding tozinameran (or famtozinameran) followed by the *in vitro* transcription of the template DNA molecule to produce tozinameran (or famtozinameran). Counterclaim Defendants' manufacture of Comirnaty® therefore infringes claims 7, 8, and 9 of the '312 patent.

48. On information and belief, Comirnaty® is formulated with a pharmaceutically acceptable carrier. Exhibit 12 (Comirnaty® package insert) at 15; Exhibit 13 (Comirnaty® Bivalent package insert) at 36. On information and belief, Counterclaim Defendants instruct those administering Comirnaty® to dilute the Comirnaty® formulation with a solution of 0.9% sodium chloride. Exhibit 12 (Comirnaty® package insert) at 2. Counterclaim Defendants' manufacture and sale of Comirnaty® therefore infringes claim 14 of the '312 patent.

49. On information and belief, when the tozinameran and famtozinameran in Comirnaty® are transcribed from their respective plasmids, a modified form of uridine, 1-methyl-3'-pseudouridylyl, is incorporated at the positions that would otherwise contain uridine residues. Exhibit 14 (WHO INN Programme Report No. 11889) at 2-4; Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 3. Accordingly, tozinameran (and famtozinameran) contains a stabilized mRNA comprising at least one nucleotide (uridine) replaced with a nucleotide analog (pseudoU). Counterclaim Defendants' manufacture of Comirnaty® therefore infringes claim 15 of the '312 patent.

50. On information and belief, Counterclaim Defendants have directly infringed and continue to directly infringe at least claims 1, 7–9, 14, and 15 of the '312 patent, either literally or

under the doctrine of equivalents, by manufacturing tozinameran and famtozinameran in the United States for use in Comirnaty® sold in the United States and outside the United States in violation of 35 U.S.C. § 271(a).

51. On information and belief, Counterclaim Defendants have induced infringement and continue to induce infringement of claim 14 of the '312 patent, either literally or under the doctrine of equivalents, by encouraging healthcare providers to formulate Comirnaty® in the United States and in this District in a manner that directly infringes claim 14 of the '312 patent in violation of 35 U.S.C. § 271(b).

52. On information and belief, Comirnaty® constitutes a material part of the invention recited in claim 14 of the '312 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Counterclaim Defendants have contributorily infringed and continue to contributorily infringe claim 14 of the '312 patent, either literally or under the doctrine of equivalents, by promoting the making and use of Comirnaty® in accordance with its approved package insert and/or Emergency Use Authorization in the United States and in this District by others, including healthcare providers, and knowing that Comirnaty® is especially made or especially adapted for use to infringe claim 14 of the '312 patent in violation of 35 U.S.C. § 271(c).

53. On information and belief, Counterclaim Defendants have infringed or will infringe one or more of the claims of the '312 patent, either literally or under the doctrine of equivalents, by importing Comirnaty® containing tozinameran (and famtozinameran) into the United States in violation of 35 U.S.C. § 271(g).

54. Counterclaim Defendants' infringement of the '312 patent has been and continues to be willful. As discussed above, Pfizer and BioNTech chose to advance BNT162b2 as their lead vaccine candidate knowing that it contains an mRNA that has a G/C content that is increased by

at least 7 percentage points compared to the original coding sequence encoding the spike glycoprotein on SARS-CoV-2. Moreover, by at least March 29, 2022, BioNTech was provided with a presentation identifying 27 patents and patent applications in CureVac's patent portfolio, including the '312 patent. D.I. 47 at 12.

55. Counterclaim Defendants continue to use the inventions claimed in the '312 patent in deliberate disregard for CureVac's patent rights.

56. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of the '312 patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties, for Counterclaim Defendants' infringement of the '312 patent.

57. Counterclaim Defendants have engaged in egregious infringement behavior with respect to the '312 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

58. Counterclaim Defendants' conduct with respect to the '312 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT II – INFRINGEMENT OF THE '312 PATENT (PROVISIONAL RIGHTS)

59. CureVac incorporates each of the above paragraphs 1–58 as though fully set forth herein.

60. The '312 patent issued from U.S. Patent Application No. 14/487,425 ("the '425 application") filed on September 16, 2014, which was filed as a division of Application No. 10/729,830 ("the '830 application") filed on December 5, 2003, which issued as U.S. Patent No. 10,188,748 ("the '748 patent"). The '830 application was filed as a continuation-in-part of an international application, PCT Application No. PCT/EP02/06180 ("the '180 PCT application"), which was filed on June 5, 2002.

61. Pursuant to 35 U.S.C. § 122(b), the '425 application published as U.S. Patent Publ. No. 2015/0104476 A1 ("the '476 publication") on April 16, 2015. A true and correct copy of the

'476 publication is attached hereto as Exhibit 16. The '476 publication contained 17 claims, numbered 29 to 45. Claims 29 and 34 recite:

> **29.** A method for producing a stabilized mRNA comprising synthesizing an mRNA encoding a native polypeptide sequence, wherein the mRNA encoding the polypeptide comprises a nucleic acid sequence that has an increased GuanineCytosine (G/C) content relative to the native nucleic acid sequence encoding the polypeptide, said relative G/C content being increased by at least 7 percentage points compared to native nucleic acid sequence encoding the polypeptide, to thereby produce a stabilized mRNA.
>
> **34.** The method of claim 29, wherein the stabilized mRNA comprises a nucleic acid sequence having at least one destabilizing sequence element (DSE) removed relative to the native mRNA encoding the polypeptide.

62. On March 4, 2014, CureVac granted BioNTech a limited non-exclusive license (that excludes uses related to infectious diseases) to patents and patent applications that include the application that published as the '476 publication. Thus, on information and belief, BioNTech had actual notice of the '476 publication. On information and belief, as a collaboration partner of BioNTech, Pfizer also had actual notice of the '476 publication.

63. On information and belief, the method which Counterclaim Defendants have used to manufacture Comirnaty® satisfies each and every element of at least claim 34 in the '476 publication. Counterclaim Defendants' actions with respect to Comirnaty® thus infringed at least claim 34 in the '476 publication under 35 U.S.C. §154(d).

64. On information and belief, the coding sequence of tozinameran has a G/C content that is increased about 19 percentage points compared to the original coding sequence for the spike glycoprotein on SARS-CoV-2, and tozinameran is more stable than the original coding sequence due to the removal of at least one destabilizing sequence element. Counterclaim Defendants' manufacture of Comirnaty® therefore infringed claim 34 in the '476 publication under 35 U.S.C. §154(d).

65. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of claim 34 in the '476 publication. CureVac is entitled to an award of a reasonable royalty for Counterclaim Defendants' infringement of claim 34 in the '476 publication.

COUNT III – INFRINGEMENT OF THE '278 PATENT

66. CureVac incorporates each of the above paragraphs 1–65 as though fully set forth herein.

67. The '278 patent is directed to methods of treating or preventing infectious diseases by administering an RNA having a unique poly-adenosine ("poly(A)") tail that results in the increased expression of the protein encoded by the RNA. The '278 patent inventors discovered that an mRNA containing a 3'-untranslated region with two poly(A) sequences separated by a sequence of from 10 to 90 nucleotides expresses more protein *in vivo* than an mRNA containing a single poly(A) tail. The '278 patent claims encompass administering this kind of mRNA to treat or prevent an infectious disease.

68. The '278 patent issued with twenty claims. Independent claim 1 recites:

> **1.** A method for treating or preventing an infectious disease, the method comprising administering an RNA molecule comprising:
>
> a) at least one open reading frame (ORF) encoding an antigen from a pathogen associated with the infectious disease; and
>
> b) a 3′-untranslated region (3′-UTR) comprising at least two poly(A) sequences, wherein at least one of the poly(A) sequences comprises at least 70 adenine nucleotides, wherein the at least two poly (A) sequence elements are separated by a nucleic acid sequence comprising from 10 to 90 nucleotides, wherein the RNA molecule is administered intramuscularly.

69. Dependent claims 13–17 serially narrow claim 1:

> **13.** The method of claim 1, wherein the open reading frame is at least partially codon-optimized.
>
> **14.** The method of claim 13, wherein the RNA molecule comprises at least one nucleotide analogue.

> **15.** The method of claim 14, wherein the at least one nucleotide analogue is a modified form of uridine.
>
> **16.** The method of claim 15, wherein the modified form of uridine is chemically altered by methylation.
>
> **17**. The method of claim 16, wherein the modified form of uridine is a naturally occurring variant of uridine.

70. Comirnaty® contains the tozinameran mRNA molecule, and in the bivalent version also contains the famtozinameran mRNA molecule, both of which contain an open reading frame (ORF) encoding the SARS CoV-2 viral spike protein antigen. Exhibit 14 (WHO INN Programme Report No. 11889) at 2 ("Codon-optimized sequence encoding full-length SARS-CoV-2 spike (S) glycoprotein"); Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("Codon-optimized sequences encoding the respective antigen of SARS-CoV-2 protein has following point mutations/deletions . . .").

71. The tozinameran mRNA molecule and the famtozinameran mRNA molecule both contain a "110-nucleotide poly(A)-tail consisting of a stretch of 30 adenosine residues, followed by a 10-nucleotide linker sequence and another 70 adenosine residues." Exhibit 14 (WHO INN Programme Report No. 11889) at 1–2; Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("A30L70 (nucleotides 4159 to 4268)").

72. The use of Comirnaty® as instructed in its package insert is a method for treating or preventing an infectious disease, involving administering the tozinameran (and famtozinameran) mRNA molecule, which contains the open reading frame (ORF) encoding the SARS CoV-2 viral spike protein antigen, which is from the pathogen SARS-CoV-2 virus associated with the infectious disease COVID-19; and which contains a 3'-untranslated region containing at least two poly(A) sequences, one of which contains 70 adenosine nucleotides, and in which the two poly(A) sequences are separated by 10 nucleotides; and which is administered

intramuscularly. For example, Section 2.2 of the Comirnaty® package insert instructs users to "[a]dminister a single 0.3 mL dose of COMIRNATY intramuscularly" (Exhibit 12 (Comirnaty® package insert) at 5), Section 11 states "[e]ach 0.3 mL dose of COMIRNATY . . . contains 30 mcg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike (S) glycoprotein SARS-CoV-2" (*id.* at 14), and Section 12 states "[t]he nucleoside-modified mRNA in COMIRNATY is formulated in lipid particles, which enable delivery of the mRNA into host cells to allow expression of the SARS-CoV-2 S antigen." *Id.* at 15; *see also* Exhibit 13 (Comirnaty® Bivalent package insert) at 17 ("COMIRNATY (COVID-19 Vaccine, mRNA) is a sterile suspension for injection for intramuscular use"). Section 12 also states that "[t]he vaccine elicits an immune response to the S antigen, which protects against COVID-19," which constitutes a method for treating or preventing an infectious disease. Exhibit 12 (Comirnaty® package insert) at 15; *see also* Exhibit 13 (Comirnaty® Bivalent package insert) at 17.

73. On information and belief, when the tozinameran and famtozinameran in Comirnaty® are transcribed from their plasmids, a modified form of uridine, 1-methyl-3'-pseudouridylyl, is incorporated at the positions that would otherwise contain uridine residues. Exhibit 14 (WHO INN Programme Report No. 11889) at 2–4; Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 3. In other words, tozinameran and famtozinameran contain an mRNA comprising at least one nucleotide (uridine) replaced with a nucleotide analog (pseudoU) that has been chemically modified by methylation.

74. On information and belief, BioNTech Manufacturing is the BLA license holder for Comirnaty®. Exhibit 17 (FDA Approval Letter) at 1. The use of Comirnaty® as instructed by Counterclaim Defendants in their package inserts satisfies each and every element of at least claims 1 and 13–17 of the '278 patent because the package inserts instruct medical professionals to

administer Comirnaty® via an intramuscular injection. Exhibit 12 (Comirnaty® package insert) at 2; Exhibit 13 (Comirnaty® Bivalent package insert) at 2. Consequently, Counterclaim Defendants have induced infringement and continue to induce infringement of at least claims 1 and 13–17 of the '278 patent, either literally or under the doctrine of equivalents, by encouraging healthcare providers to use Comirnaty® in the United States and in this District in a manner that directly infringes the '278 patent. Indeed, the only use of Comirnaty® instructed in its package insert infringes the claims of the '278 patent. Counterclaim Defendants have intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '278 patent and with knowledge that their acts are encouraging infringement, in violation of 35 U.S.C. § 271(b).

75. Prior to approval of the BLA, the use of Comirnaty® pursuant to all of the Counterclaim Defendants' Emergency Use Authorizations infringed the claims of the '278 patent for the same reasons. For example, Counterclaim Defendants published a "Fact Sheet" that instructs the use of booster shots in individuals 12 years of age or older who have completed their primary vaccination series and explains that Counterclaim Defendants' vaccine "has been shown to prevent COVID-19." Exhibit 18 (Fact Sheet) at 4. Booster doses can comprise the administration of a vaccine identical in dosage strength and composition to doses of the primary vaccination series of Comirnaty®. *See* Press Release, Pfizer and BioNTech Announce Phase 3 Trial Data Showing High Efficacy of a Booster Dose of Their COVID-19 Vaccine (Oct. 21, 2021), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-phase-3-trial-data-showing (available in archival form at https://perma.cc/94KH-8R2B). Booster doses can also comprise a mixture of 15 micrograms of tozinameran and 15 micrograms of famtozinameran formulated in the same manner as other doses of Comirnaty®. *See* Press Release,

Pfizer and BioNTech Granted FDA Emergency Use Authorization of Omicron BA.4/BA.5-Adapted Bivalent COVID-19 Vaccine Booster for Ages 12 Years and Older (Aug. 31, 2022), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-granted-fda-emergency-use-authorization (available in archival form at https://perma.cc/GL9T-U2GE).

76. On information and belief, Comirnaty® constitutes a material part of the invention in one or more claims of the '278 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Counterclaim Defendants have contributorily infringed and continue to contributorily infringe at least claims 1 and 13–17 of the '278 patent, either literally or under the doctrine of equivalents, by promoting the making and use of Comirnaty® in accordance with its approved package inserts and/or Emergency Use Authorizations in the United States and in this District by healthcare providers, and knowing that Comirnaty® is especially made or especially adapted for use to infringe the '278 patent in violation of 35 U.S.C. § 271(c).

77. On information and belief, Counterclaim Defendants have knowledge of the '278 patent and knowledge that their actions promoting the use of Comirnaty® in the United States induces infringement and contributorily infringes the '278 patent.

78. For example, BioNTech was aware of the applications that led to the '278 patent. On June 26, 2018, BioNTech filed an Information Disclosure Statement in U.S. Patent App. No. 15/217,555, a patent application titled "Modification of RNA, Producing an Increased Transcript Stability and Translation Efficiency," that listed Patent Cooperation Treaty Application Publ. No. WO 2016/091391 ("the '391 publication"), which is the publication of the application that led to the '278 patent. Exhibit 19 (BioNTech IDS) at 4. ("2016/091391 WO A1 2016-06-16 Curevac AG"). Also on June 26, 2018, BioNTech provided a copy of the '391 publication to the U.S. Patent & Trademark Office. Despite their knowledge of the inventions claimed in the '391 publication,

Counterclaim Defendants chose to utilize a 3′-untranslated region (3'-UTR) comprising a poly(A) sequence that contains 30 adenosine residues, followed by a 10-nucleotide linker sequence and another 70 adenosine residues. On information and belief, Counterclaim Defendants knew that choosing that design would infringe claims that would issue from the '391 publication. Moreover, by at least March 29, 2022, BioNTech was provided with a presentation identifying 27 patents and patent applications in CureVac's patent portfolio, including the '287 patent. D.I. 47 at 12. Counterclaim Defendants' infringement of the '278 patent has thus been willful.

79. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of the '278 patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties for Counterclaim Defendants' infringement of the '278 patent.

80. Counterclaim Defendants have engaged in egregious infringement behavior with respect to the '278 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

81. Counterclaim Defendants' conduct with respect to the '278 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT IV – INFRINGEMENT OF THE '492 PATENT

82. CureVac incorporates each of the above paragraphs 1–81 as though fully set forth herein.

83. The application that led to the issuance of the '492 patent was filed as a division of the application that led to the '278 patent, and therefore the '492 patent shares a common specification with the '278 patent. The '492 patent, like the '278 patent, is directed to methods of treating or preventing infectious diseases by administering an RNA having a unique poly(A) tail that results in the increased expression of the protein encoded by the RNA.

84. The '492 patent issued with thirty claims. Independent claim 25 recites:

25. A method for increasing protein production from a RNA molecule comprising providing the RNA molecule formulated in a pharmaceutical composition, where the RNA molecule comprises:

a) a 5′-cap structure;

b) at least one open reading frame (ORF) encoding a protein; and

c) a heterologous 3′-untranslated region (3′-UTR) comprising at least a first and a second poly(A) sequence, wherein:

(i) the first poly(A) sequence comprises at least 20 adenine nucleotides; and

(ii) the second poly(A) sequence comprises at least 70 adenine nucleotides,

wherein the first and the second poly(A) sequences are separated by a nucleic acid sequence consisting of 10 nucleotides and having no more than 2 consecutive adenine nucleotides,

wherein the ORF encoding the protein has a G/C content that is increased by at least 15% relative to a corresponding reference ORF encoding the protein,

wherein the RNA molecule yields increased protein production when expressed in a cell or an organism in comparison to a reference nucleic acid molecule comprising an identical nucleic acid sequence as the RNA molecule but lacking a second poly(A) sequence.

85. Dependent claims 26–30 serially narrow claim 25:

26. The method of claim 25, wherein the ORF encoding the protein is an antigen.

27. The method of claim 26, wherein the antigen is a viral antigen.

28. The method of claim 27, wherein the RNA molecule comprises at least one nucleotide analogue, which is a naturally occurring variant of uridine.

29. The method of claim 28, wherein the RNA molecule is complexed with a cationic carrier or a polycationic carrier.

30. The method of claim 29, wherein the cationic or polycationic compound comprises a cationic lipid.

86. Comirnaty® contains the tozinameran mRNA molecule, and in the bivalent version also contains the famtozinameran mRNA molecule, both of which contain a “cap” at the 5′ end of

the molecule. Exhibit 14 (WHO INN Programme Report No. 11889) at 1 ("A modified 5'-cap1 structure (m7G+m3'-5'-ppp-5'-Am)"); Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 6 ("Sequence length: 4269, which includes 'Cap-' to denote the presence of the 5'-cap analog").

87. Comirnaty® contains the tozinameran mRNA molecule, and in the bivalent version also contains the famtozinameran mRNA molecule, both of which contain an open reading frame (ORF) encoding the SARS CoV-2 viral spike protein antigen. Exhibit 14 (WHO INN Programme Report No. 11889) at 2 ("Codon-optimized sequence encoding full-length SARS-CoV-2 spike (S) glycoprotein"); Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("Codon-optimized sequences encoding the respective antigen of SARS-CoV-2 protein has following point mutations/deletions . . .").

88. Comirnaty® contains the tozinameran mRNA molecule, and in the bivalent version also contains the famtozinameran mRNA molecule, both of which contain a "110-nucleotide poly(A)-tail consisting of a stretch of 30 adenosine residues, followed by a 10-nucleotide linker sequence and another 70 adenosine residues." Exhibit 14 (WHO INN Programme Report No. 11889) at 1–2; Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("A30L70 (nucleotides 4159 to 4268)"). The sequence of the 10-nucleotide linker is "GCAΨAΨGACΨ." Exhibit 14 (WHO INN Programme Report No. 11889) at 4 (nucleotides 4188 to 4197); Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 6 (nucleotides 4205 to 4214)").

89. On information and belief, the coding sequence of tozinameran has a G/C content that is increased by about 19 percentage points compared to the original coding sequence for the spike glycoprotein on SARS-CoV-2, and the coding sequence of famtozinameran has a G/C

content that is increased by about 19 percentage points compared to the original coding sequence for the spike glycoprotein on BA.4 SARS-CoV-2 variant and has a G/C content that is increased by about 19 percentage points compared to the original coding sequence for the spike glycoprotein on BA.5 SARS-CoV-2 variant.

90. On information and belief, when Comirnaty® containing tozinameran is administered to an organism, the antigen produced by tozinameran (*i.e.,* a coronavirus spike protein) is produced.at a higher level than it would be if Comirnaty® contained a form of tozinameran that lacks the second poly(A).

91. On information and belief, when the tozinameran and famtozinameran in Comirnaty® are transcribed from their respective plasmids, a modified form of uridine, 1-methyl-3'-pseudouridylyl, a naturally occurring variant of uridine, is incorporated at the positions that would otherwise contain uridine residues. Exhibit 14 (WHO INN Programme Report No. 11889) at 2-4; Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 3.

92. On information and belief, the mRNAs in Comirnaty® are complexed with lipid nanoparticles containing ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), which is also known as "ALC-0315." Exhibit 12 (Comirnaty® package insert) at 15; Exhibit 13 (Comirnaty® Bivalent package insert) at 36. ALC-0315 is a cationic lipid. Exhibit 20 (Rapporteur Review) at 188 ("The ALC-0315 novel excipient is a cationic lipid containing a tertiary amine and two ester moieties").

93. On information and belief, BioNTech Manufacturing is the BLA license holder for Comirnaty®. Exhibit 17 (FDA Approval Letter) at 1. The use of Comirnaty® as instructed by Counterclaim Defendants in their package inserts satisfies each and every element of at least claims 25–30 of the '492 patent. Counterclaim Defendants' package inserts instruct medical professionals

to administer Comirnaty® via an intramuscular injection. Exhibit 12 (Comirnaty® package insert) at 2; Exhibit 13 (Comirnaty® Bivalent package insert) at 2. Consequently, Counterclaim Defendants have induced infringement and continue to induce infringement of at least claims 25–30 of the '492 patent, either literally or under the doctrine of equivalents, by encouraging healthcare providers to use Comirnaty® in the United States and in this District in a manner that directly infringes the claims in the '492 patent. Indeed, the only use of Comirnaty® instructed in its package inserts infringes the claims of the '492 patent. Counterclaim Defendants have intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '492 patent and with knowledge that their acts are encouraging infringement, in violation of 35 U.S.C. § 271(b).

94. Prior to approval of the BLA, the use of Comirnaty® pursuant to all of Counterclaim Defendants' Emergency Use Authorizations infringed the claims of the '492 patent for the same reasons. For example, Counterclaim Defendants published a "Fact Sheet" that instructs the use of booster shots in individuals 12 years of age or older who have completed their primary vaccination series and explains that Counterclaim Defendants' vaccine "has been shown to prevent COVID-19." Exhibit 18 (Fact Sheet) at 4. Booster doses can comprise the administration of a vaccine identical in dosage strength and composition to doses of the primary vaccination series of Comirnaty®. *See* Press Release, Pfizer and BioNTech Announce Phase 3 Trial Data Showing High Efficacy of a Booster Dose of Their COVID-19 Vaccine (Oct. 21, 2021), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-phase-3-trial-data-showing (available in archival form at https://perma.cc/94KH-8R2B). Booster doses can also comprise a mixture of 15 micrograms of tozinameran and 15 micrograms of

famtozinameran formulated in the same manner as other doses of Comirnaty®. *See* Press Release, Pfizer and BioNTech Granted FDA Emergency Use Authorization of Omicron BA.4/BA.5-Adapted Bivalent COVID-19 Vaccine Booster for Ages 12 Years and Older (Aug. 31, 2022), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-granted-fda-emergency-use-authorization (available in archival form at https://perma.cc/GL9T-U2GE).

95. On information and belief, Comirnaty® constitutes a material part of the invention of one or more claims of the '492 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Counterclaim Defendants have contributorily infringed and continue to contributorily infringe at least claims 25–30 of the '492 patent, either literally or under the doctrine of equivalents, by promoting the making and use of Comirnaty® in accordance with its approved package inserts and/or Emergency Use Authorizations in the United States and in this District by healthcare providers, and knowing that Comirnaty® is especially made or especially adapted for use to infringe the '492 patent in violation of 35 U.S.C. § 271(c).

96. On information and belief, Counterclaim Defendants have knowledge of the '492 patent and knowledge that their actions promoting the use of Comirnaty® in the United States induces infringement and contributorily infringes the '492 patent.

97. For example, BioNTech was aware of the applications that led to the '492 patent. On June 26, 2018, BioNTech filed an Information Disclosure Statement in U.S. Patent App. No. 15/217,555, a patent application titled "Modification of RNA, Producing an Increased Transcript Stability and Translation Efficiency," that listed the '391 publication, which is the publication of a related application that led to the '492 patent. Exhibit 19 (BioNTech IDS) at 4. ("2016/091391 WO A1 2016-06-16 Curevac AG"). Also on June 26, 2018, BioNTech provided a copy of the '391 publication to the U.S. Patent & Trademark Office. Despite their knowledge of CureVac's '391

publication, BioNTech and Pfizer chose to utilize a poly(A) sequence that contains 30 adenosine residues, followed by a 10-nucleotide linker sequence and another 70 adenosine residues. On information and belief, BioNTech and Pfizer knew that choosing that poly(A) design would infringe claims that issue from the '391 publication and related applications. Moreover, by at least March 29, 2022, BioNTech was provided with a presentation identifying 27 patents and patent applications in CureVac's patent portfolio, including the '492 patent. D.I. 47 at 12. Counterclaim Defendants' infringement of the '492 patent has been willful.

98. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of the '492 patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties for Counterclaim Defendants' infringement of the '492 patent.

99. Counterclaim Defendants have engaged in egregious infringement behavior with respect to the '492 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

100. Counterclaim Defendants' conduct with respect to the '492 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT V – INFRINGEMENT OF THE '920 PATENT

101. CureVac incorporates each of the above paragraphs 1–100 as though fully set forth herein.

102. The application that led to the issuance of the '920 patent was filed as a division of the application that led to the '492 patent, which was a division of the application that led to the '278 patent. The '920 patent therefore shares a common specification with the '492 and '278 patents. The '920 patent, like the '278 patent, is directed to methods of treating or preventing infectious diseases by administering an RNA having a unique poly(A) tail that results in the increased expression of the protein encoded by the RNA.

103. The '920 patent issued with twenty-eight claims. Independent claim 23 recites:

23. A method for stimulating an immune response in an organism, the method comprising administering to the organism a RNA molecule comprising:

a) a 5′-cap structure;

b) an open reading frame encoding a coronavirus antigen; and

c) a heterologous 3′-untranslated region comprising a first and a second poly(A) sequence, wherein:

(i) the first poly(A) sequence comprises at least 20 adenine nucleotides; and

(ii) the second poly(A) sequence comprises at least 70 adenine nucleotides,

wherein the first and the second poly(A) sequences are separated by a nucleic acid sequence comprising 10 nucleotides and having no more than 2 consecutive adenine nucleotides,

wherein the RNA molecule is administered intramuscularly;

wherein when the RNA molecule is expressed in the organism, the RNA molecule yields increased expression of the antigen encoded by the open reading frame in comparison to a reference nucleic acid molecule comprising an identical nucleic acid sequence as the RNA molecule but lacking the second poly(A) sequence;

wherein the RNA molecule comprises at least one nucleotide analog comprising a modified form of uridine chemically altered by methylation; and

wherein the RNA molecule is transfected into cells of the organism in a nanoparticle.

104. Dependent claims 24–26 narrow claim 23:

24. The method of claim 23, wherein the open reading frame has a guanidine/cytosine content that is increased by at least 15% relative to a corresponding reference open reading frame.

25. The method of claim 23, wherein the RNA molecule yields an increased immune response in comparison to an intramuscular injection of a reference nucleic acid molecule comprising an identical nucleic acid sequence as the RNA molecule but lacking the second poly(A) sequence.

26. The method of claim 25, wherein when administered intramuscularly, the RNA molecule yields an increased neutralizing antibody response in comparison to an intramuscular injection of a reference nucleic acid molecule comprising an identical nucleic acid sequence as the RNA molecule but lacking the second poly(A) sequence.

105. Comirnaty® contains the tozinameran mRNA molecule, and in the bivalent version also contains the famtozinameran mRNA molecule, both of which contain an open reading frame (ORF) encoding the SARS CoV-2 viral spike protein antigen. Exhibit 14 (WHO INN Programme Report No. 11889) at 2 ("Codon-optimized sequence encoding full-length SARS-CoV-2 spike (S) glycoprotein"); Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("Codon-optimized sequences encoding the respective antigen of SARS-CoV-2 protein has following point mutations/deletions . . .").

106. The use of Comirnaty® as instructed in its package inserts is a method for treating or preventing an infectious disease, involving administering the tozinameran (and famtozinameran) mRNA molecule, which contains the open reading frame (ORF) encoding the SARS CoV-2 viral spike protein antigen, which is from the pathogen SARS-CoV-2 virus associated with the infectious disease COVID-19; and which contains a 3'-untranslated region containing at least two poly(A) sequences, one of which contains 70 adenine nucleotides, and in which the two poly(A) sequences are separated by 10 nucleotides; and which is administered intramuscularly. For example, Section 2.2 of the Comirnaty® package insert instructs users to "[a]dminister a single 0.3 mL dose of COMIRNATY intramuscularly" (Exhibit 12 (Comirnaty® package insert) at 5), Section 11 states "[e]ach 0.3 mL dose of COMIRNATY . . . contains 30 mcg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike (S) glycoprotein SARS-CoV-2" (*id.* at 14), and Section 12 states "[t]he nucleoside-modified mRNA in COMIRNATY is formulated in lipid particles, which enable delivery of the mRNA into host cells to allow expression of the SARS-CoV-2 S antigen." *Id.* at 15; *see also* Exhibit 13 (Comirnaty® Bivalent package insert) at 17 ("COMIRNATY (COVID-19 Vaccine, mRNA) is a sterile suspension for injection for intramuscular use"). Section 12 also states that "[t]he vaccine elicits

an immune response to the S antigen, which protects against COVID-19," which constitutes a method for treating or preventing an infectious disease. Exhibit 12 (Comirnaty® package insert) at 15; *see also* Exhibit 13 (Comirnaty® Bivalent package insert) at 17.

107. Comirnaty® contains the tozinameran mRNA molecule, and in the bivalent version also contains the famtozinameran mRNA molecule, both of which contain a "cap" at the 5′ end of the molecule. Exhibit 14 (WHO INN Programme Report No. 11889) at 1 ("A modified 5'-cap1 structure (m7G+m3'-5'-ppp-5'-Am)"); Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 6 ("Sequence length: 4269, which includes 'Cap-' to denote the presence of the 5'-cap analog").

108. Comirnaty® contains the tozinameran mRNA molecule, and in the bivalent version also contains the famtozinameran mRNA molecule, both of which contain a "110-nucleotide poly(A)-tail consisting of a stretch of 30 adenosine residues, followed by a 10-nucleotide linker sequence and another 70 adenosine residues." Exhibit 14 (WHO INN Programme Report No. 11889) at 1–2; Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("A30L70 (nucleotides 4159 to 4268)."). The sequence of the 10-nucleotide linker is "GCAΨAΨGACΨ." Exhibit 14 (WHO INN Programme Report No. 11889) at 4 (nucleotides 4188 to 4197); Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 6 (nucleotides 4205 to 4214)").

109. On information and belief, when the tozinameran and famtozinameran in Comirnaty® are transcribed from their respective plasmids, a modified form of uridine, 1-methyl-3'-pseudouridylyl, is incorporated at the positions that would otherwise contain uridine residues. Exhibit 14 (WHO INN Programme Report No. 11889) at 2-4; Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 3.

110. On information and belief, when Comirnaty® containing tozinameran is administered to an organism, the antigen produced by tozinameran (*i.e.,* a coronavirus spike protein) is produced at a higher level than it would be if Comirnaty® contained a form of tozinameran that lacks the second poly(A).

111. On information and belief, the mRNAs in Comirnaty® are complexed with lipid nanoparticles containing ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), which is also known as "ALC-0315." Exhibit 12 (Comirnaty® package insert) at 15; Exhibit 13 (Comirnaty® Bivalent package insert) at 36. ALC-0315 is a cationic lipid. Exhibit 20 (Rapporteur Review) at 188 ("The ALC-0315 novel excipient is a cationic lipid containing a tertiary amine and two ester moieties").

112. On information and belief, when Comirnaty® containing tozinameran is administered intramuscularly to an organism, the antigen produced by tozinameran (*i.e.,* a coronavirus spike protein) elicits an immune response that is higher compared to the immune response that would be produced by the intramuscular administration of Comirnaty® containing a form of tozinameran that lacks the second poly(A). On information and belief, when Comirnaty® containing tozinameran is administered intramuscularly to an organism, the amount of neutralizing antibodies produced by tozinameran (*i.e.,* a coronavirus spike protein) is increased compared to the amount of neutralizing antibodies that would result from the intramuscular administration of Comirnaty® containing a form of tozinameran that lacks the second poly(A).

113. On information and belief, the coding sequence of tozinameran has a G/C content that is increased by about 19 percentage points compared to the original coding sequence for the spike glycoprotein on SARS-CoV-2, and the coding sequence of famtozinameran has a G/C content that is increased by about 19 percentage points compared to the original coding sequence

for the spike glycoprotein on BA.4 SARS-CoV-2 variant and has a G/C content that is increased by about 19 percentage points compared to the original coding sequence for the spike glycoprotein on BA.5 SARS-CoV-2 variant.

114. On information and belief, BioNTech Manufacturing is the holder of the FDA's Emergency Use Authorization for Comirnaty®. Exhibit 17 (FDA Approval Letter) at 1. Use of Comirnaty® as instructed by Counterclaim Defendants in their package inserts satisfies each and every element of at least claims 23–36 of the '920 patent. The Comirnaty® package insert instructs medical professionals to administer Comirnaty® via an intramuscular injection. Exhibit 12 (Comirnaty® package insert) at 2; Exhibit 13 (Comirnaty® Bivalent package insert) at 2. Consequently, Counterclaim Defendants have induced infringement and continue to induce infringement of at least claims 23–36 of the '920 patent, either literally or under the doctrine of equivalents, by encouraging healthcare providers to use Comirnaty® in the United States and in this District in a manner that directly infringes the '920 patent. Indeed, the only use of Comirnaty® instructed in its package inserts infringes the claims of the '920 patent. Counterclaim Defendants have intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '920 patent and with knowledge that their acts are encouraging infringement, in violation of 35 U.S.C. § 271(b).

115. Prior to approval of the BLA, the use of Comirnaty® pursuant to all of Counterclaim Defendants' Emergency Use Authorizations infringed the claims of the '920 patent for the same reasons. For example, Counterclaim Defendants published a "Fact Sheet" that instructs the use of booster shots in individuals 12 years of age or older who have completed their primary vaccination series and explains that Comirnaty® "has been shown to prevent COVID-19." Exhibit 18 (Fact

Sheet) at 4. Booster doses can comprise the administration of a vaccine identical in dosage strength and composition to doses of the primary vaccination series of Comirnaty®. *See* Press Release, Pfizer and BioNTech Announce Phase 3 Trial Data Showing High Efficacy of a Booster Dose of Their COVID-19 Vaccine (Oct. 21, 2021), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-phase-3-trial-data-showing (available in archival form at https://perma.cc/94KH-8R2B). Booster doses can also comprise a mixture of 15 micrograms of tozinameran and 15 micrograms of famtozinameran formulated in the same manner as other doses of Comirnaty®. *See* Press Release, Pfizer and BioNTech Granted FDA Emergency Use Authorization of Omicron BA.4/BA.5-Adapted Bivalent COVID-19 Vaccine Booster for Ages 12 Years and Older (Aug. 31, 2022), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-granted-fda-emergency-use-authorization (available in archival form at https://perma.cc/GL9T-U2GE).

116. On information and belief, Comirnaty® constitutes a material part of the invention of one or more claims of the '920 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Counterclaim Defendants have contributorily infringed and continue to contributorily infringe at least claims 23–36 of the '920 patent, either literally or under the doctrine of equivalents, by promoting the making and use of Comirnaty® in accordance with its package inserts and/or Emergency Use Authorizations in the United States and in this District by healthcare providers, and knowing that Comirnaty® is especially made or especially adapted for use to infringe the '920 patent in violation of 35 U.S.C. § 271(c).

117. On information and belief, Counterclaim Defendants have knowledge of the '920 patent and knowledge that their actions promoting the use of Comirnaty® in the United States induces infringement and contributorily infringes the '920 patent.

118. BioNTech was aware of the applications that led to the '920 patent. On June 26, 2018, BioNTech filed an Information Disclosure Statement in U.S. Patent App. No. 15/217,555, a patent application titled "Modification of RNA, Producing an Increased Transcript Stability and Translation Efficiency," that listed the '391 publication, which is the publication of a related application that led to the '920 patent. Exhibit 19 (BioNTech IDS) at 4. ("2016/091391 WO A1 2016-06-16 Curevac AG"). Also on June 26, 2018, BioNTech provided a copy of the '391 publication to the U.S. Patent & Trademark Office. Despite their knowledge of CureVac's '391 publication, Counterclaim Defendants chose to utilize a poly(A) sequence that contains 30 adenosine residues, followed by a 10-nucleotide linker sequence and another 70 adenosine residues. On information and belief, Counterclaim Defendants knew that choosing that poly(A) design would infringe claims that issue from the '391 publication and related applications. Moreover, by at least March 29, 2022, BioNTech was provided with a presentation identifying 27 patents and patent applications in CureVac's patent portfolio, including the application that led to the issuance of the '920 patent. D.I. 47 at 12. Counterclaim Defendants' infringement of the '920 patent has been willful.

119. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of the '920 patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties for Counterclaim Defendants' infringement of the '920 patent.

120. Counterclaim Defendants have engaged in egregious infringement behavior with respect to the '920 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

121. Counterclaim Defendants' conduct with respect to the '920 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT VI – INFRINGEMENT OF THE '070 PATENT

122. CureVac incorporates each of the above paragraphs 1–121 as though fully set forth herein.

123. The '070 patent is directed to methods for producing and purifying RNA to prepare pharmaceutical-grade RNA on a commercial scale. The '070 patent describes methods including the steps of providing DNA encoding the RNA, transcribing the DNA to produce RNA, and purifying the transcribed RNA by one or more steps of tangential flow filtration.

124. The '070 patent issued with 24 claims. Independent claim 1 recites:

> **1.** A method for producing and purifying a RNA, comprising the steps of
>
> A) providing a plasmid DNA encoding the RNA by
>
> A1) linearizing the plasmid DNA in a linearization reaction;
>
> A2) optionally terminating the linearization reaction; and
>
> A3) diafiltering and/or concentrating and/or purifying the linearization reaction comprising linearized plasmid DNA by one or more steps of tangential flow filtration TFF) using a TFF membrane cassette;
>
> B) transcribing the linearized DNA to yield a solution comprising a transcribed RNA; and
>
> C) diafiltering and/or concentrating and/or purifying the solution comprising the transcribed RNA by one or more steps of TFF, optionally a TFF membrane cassette.

125. Dependent claims 2 and 3 serially narrow claim 1:

> **2.** The method according to claim 1, wherein step C) comprises at least one diafiltration step using TFF and/or at least one concentration step using TFF.
>
> **3.** The method according to claim 2, wherein the at least one diafiltration step using TFF in step C) comprises diafiltration with an aqueous salt solution.

126. On information and belief, the tozinameran and famtozinameran in Comirnaty® are manufactured by a method that includes linearizing the circular plasmid DNAs that encode the tozinameran and famtozinameran mRNAs, followed by ultrafiltration/diafiltration with TFF using

a TFF membrane cassette. Exhibit 20 (Rapporteur Review) at 28–29 ("Linear DNA Template Manufacturing: . . . Following fermentation, the cells are harvested and chemically lysed to recover the plasmid DNA. After this lysis step, the circular plasmid DNA is purified by ultrafiltration/diafiltration and chromatography. Following purification, the circular plasmid DNA is incubated with a restriction enzyme, Eam1104I or equivalent, in order to linearize the plasmid followed by ultrafiltration/diafiltration"); Exhibit 21 (Equipment Annex) at 1, Table 1 ("UFDF Purification | Millipore Cogent ultrafiltration system . . .• Sartocube ECO membrane (stabilized cellulose) • Millipore cassette holder (SS)").

127. On information and belief, the tozinameran and famtozinameran in Comirnaty® are manufactured by a method that further includes the step of transcribing the linearized DNA to produce a solution that contains the transcribed RNA (either tozinameran or famtozinameran). Exhibit 20 (Rapporteur Review) at 15 ("The RNA is first synthesized via an in vitro transcription (IVT) followed by DNase I and proteinase K digestion steps, which aid in purification"); *id.* ("The primary objective of the IVT step is to synthesize RNA for drug substance production"). The transcribed RNA is purified using TFF. Exhibit 22 (EU Contract) at 61 (Manufacturing Process | In vitro transcription and tangential flow filtration (IVT/TFF)"); Exhibit 20 (Rapporteur Review) at 15 ("The crude RNA is then purified through a 2-stage ultrafiltration/diafiltration (UFDF)").

128. On information and belief, the tozinameran and famtozinameran in Comirnaty® are manufactured by a method that includes diafiltration of the transcribed RNA using an aqueous salt solution. Exhibit 20 (Rapporteur Review) at 17 ("To prepare for the UFDF step, the sanitized UFDF membranes are equilibrated with diafiltration 1 buffer (200 mM ammonium sulfate, 10 mM HEPES, 0.1 mM EDTA, pH 7.0) . . . Prior to UFDF, the post-proteinase K pool is diluted 2-fold with an ammonium sulfate dilution buffer (400 mM ammonium sulfate, 10 mM HEPES, 0.1 mM

EDTA, pH 7.0). The diluted proteinase K pool then undergoes a 2-stage diafiltration; first with a minimum of 5 diavolumes (DV) using diafiltration 1 buffer followed by a minimum of 10 diavolumes using formulation buffer (10 mM HEPES,0.1 mM EDTA, pH 7.0)").

129. Thus, on information and belief, the method Counterclaim Defendants use to manufacture the tozinameran and famtozinameran in Comirnaty® satisfies all of the limitations of at least claims 1–3 of the '070 patent for all of the reasons described above.

130. Counterclaim Defendants have directly infringed and continue to directly infringe at least claims 1–3 of the '070 patent, either literally or under the doctrine of equivalents, by manufacturing the RNA in Comirnaty® in the United States, in violation of 35 U.S.C. § 271(a).

131. On information and belief, Counterclaim Defendants have infringed or will infringe at least claims 1–3 of the '070 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271(g), by importing tozinameran and/or famtozinameran manufactured outside of the United States.

132. Counterclaim Defendants' infringement of the '070 patent has been willful. As discussed above, Pfizer and BioNTech chose to advance BNT162b2 as their lead vaccine candidate knowing that it is manufactured using the steps recited in the claims of the '070 patent.

133. Counterclaim Defendants continue to use the inventions claimed in the '070 patent in deliberate disregard for CureVac's patent rights.

134. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of the '070 patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties, for Counterclaim Defendants' infringement of the '070 patent.

135. Counterclaim Defendants have engaged in egregious infringement behavior with respect to the '070 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

136. Counterclaim Defendants' conduct with respect to the '070 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT VII – INFRINGEMENT OF THE '493 PATENT

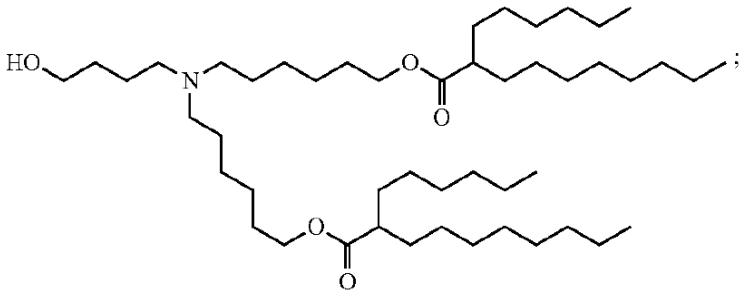
137. CureVac incorporates each of the above paragraphs 1–136 as though fully set forth herein.

138. The '493 patent is directed to an RNA-based vaccine composition for treating coronavirus infections, in particular SARS-CoV-2 infections, that contains an mRNA that encodes the protein designed to mimic the shape of the pre-fusion form of the spike protein on the SARS-CoV-2 virus. The '493 patent also describes formulating the mRNA in a lipid nanoparticle ("LNP") containing at least one cationic lipid, at least one neutral lipid, at least one steroid or steroid analog, preferably cholesterol, and at least one polymer-conjugated lipid, preferably a polyethylene glycol-lipid ("PEG-lipid").

139. The '493 patent issued with 27 claims. Independent claim 1 recites:

> **1.** A composition comprising a mRNA comprising:
>
> (a) at least one coding sequence encoding a SARS-CoV-2 spike protein (S) at least 95% identical to SEQ ID NO:10 that is a pre-fusion stabilized spike protein (S_stab) comprising a pre-fusion stabilizing K986P and V987P mutation;
>
> (b) at least one heterologous untranslated region (UTR); and
>
> (c) at least one pharmaceutically acceptable carrier, wherein the mRNA is complexed or associated with lipid nanoparticles (LNP) and wherein the LNP comprises:
>
> (i) at least one cationic lipid according to formula III-3:

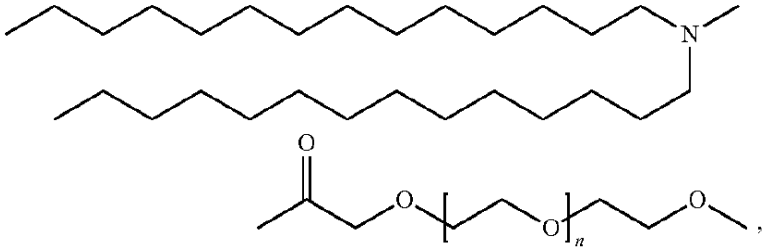
(III-3)



(ii) at least one neutral lipid, comprising 1,2-distearoylsn-glycero-3-phosphocholine (DSPC);

(iii) at least one steroid, comprising cholesterol; and (iv) at least one PEG-lipid according to formula IVa:

IVa



wherein n has a mean value ranging from 30 to 60,

wherein (i) to (iv) are in a molar ratio of about 20-60% cationic lipid, 5-25% neutral lipid, 25-55% sterol, and 0.5-15% PEG-lipid.

140. Claims 11, 13, 18, and 22 further narrow claim 1:

11. The composition of claim 1, wherein the mRNA comprises a nucleotide analog.

13. The composition of claim 1, wherein the mRNA is a purified mRNA that has been purified by RP-HPLC and/or TFF.

18. The composition of claim 11, wherein the mRNA comprises a 1-methylpseudouridine substitution.

22. The composition of claim 1, wherein the LNP comprises a molar ratio of approximately 47.4:10:40.9:1.7 of cationic lipid:DSPC:cholesterol:PEG.

141. On information and belief, Comirnaty® is a pharmaceutical composition containing an mRNA (tozinameran) having at least one coding sequence encoding a SARS-CoV-2 spike protein (S) that is at least 95% identical to SEQ ID NO:10 in the '493 patent, which is a pre-fusion stabilized spike protein (S_stab) containing pre-fusion stabilizing K986P and V987P mutations. Exhibit 14 (WHO INN Programme Report 11889) at 1–2 ("S glycoprotein sequence containing mutations K986P and V987P," which is a "[c]odon-optimized sequence encoding full-length SARS-CoV-2 spike (S) glycoprotein containing mutations K986P and V987P to ensure the S glycoprotein remains in an antigenically optimal pre-fusion conformation," located at nucleotide positions 103-3879). On information and belief, the mRNA in Comirnaty® contains at least one heterologous untranslated region, the 5′-untranslated region derived from human alpha-globin RNA with an optimized Kozak sequence. *Id.* at 1.

142. On information and belief, each 0.3 milliliter dose of Comirnaty® contains tozinameran, or a combination of tozinameran and famtozinameran, complexed with the following lipid nanoparticle components: (i) ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) at a concentration of 7.17 mg/mL, which is the compound of formula III-3 recited in claim 1 and is also known as "ALC-0315"; (ii) 1,2-distearoylsn-glycero-3-phosphocholine at a concentration of 1.56 mg/mL, which is a neutral lipid; (iii) cholesterol at a concentration of 3.1 mg/mL; and (iv) 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, at a concentration of 0.89 mg/mL, which is a pegylated lipid of formula IVa recited in claim 1 and is also known as "ALC-0159." Exhibit 20 (Rapporteur Review) at 113 (Table P.2-1). On information and belief, the components of the lipid nanoparticles in Comirnaty® are present in a molar ratio of cationic lipid:DSPC:cholesterol:PEG-lipid of approximately 47.4:10:40.9:1.7. *Id.* at 116 ("In vivo

experiments after IM administration of the final ALC-0315/ALC-0159/DSPC/cholesterol LNP at molar ratio 47.5/10/40.7/1.8, confirmed expression of mRNA for this route of administration").

143. On information and belief, when the tozinameran and famtozinameran in Comirnaty® are transcribed from their respective plasmids, a modified form of uridine, 1-methyl-3'-pseudouridylyl, is incorporated at the positions that would otherwise contain uridine residues. Exhibit 14 (WHO INN Programme Report No. 11889) at 2–5; Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 3. In other words, tozinameran and famtozinameran contain an mRNA having a 1-methylpseudouridine substitution.

144. On information and belief, tozinameran and famtozinameran are transcribed from their linear DNA plasmids using an in vitro transcription (IVT) step followed by purification using tangential flow filtration ("TFF"). Exhibit 22 (EU Contract) at 61 (Manufacturing Process | In vitro transcription and tangential flow filtration (IVT/TFF)").

145. The package inserts for Comirnaty® instruct a health care provider to "[a]dminister a single 0.3 mL dose of COMIRNATY intramuscularly." Exhibit 12 (Comirnaty® package insert) at 5; *see also* Exhibit 13 (Comirnaty® Bivalent package insert) at 7 ("After withdrawing a single 0.3 mL dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent, administer immediately").

146. Thus, on information and belief, Comirnaty® satisfies all of the limitations of at least claims 1, 11, 13, 18, and 22 of the '493 patent for all of the reasons described above.

147. On information and belief, Counterclaim Defendants have directly infringed and continue to directly infringe at least claims 1, 11, 13, 18, and 22 of the '493 patent, either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing Comirnaty® in the United States and in this District without authority, in violation of 35 U.S.C. § 271(a).

148. On information and belief, Counterclaim Defendants have induced infringement and continue to induce infringement of at least claims 1, 11, 13, 18, and 22 of the '493 patent, either literally or under the doctrine of equivalents, by encouraging others, including but not limited to healthcare providers and patients, to use Comirnaty® (containing tozinameran or a combination of tozinameran and famtozinameran) in the United States and in this District in a manner that would directly infringe the '493 patent. Counterclaim Defendants have intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '493 patent and with knowledge that their acts are encouraging infringement, in violation of 35 U.S.C. § 271(b).

149. On information and belief, Comirnaty® constitutes a material part of the invention of at least claims 1, 11, 13, 18, and 22 of the '493 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Counterclaim Defendants have contributorily infringed and continue to contributorily infringe at least claims 1, 11, 13, 18, and 22 of the '493 patent, either literally or under the doctrine of equivalents, by promoting the use of Comirnaty® in accordance with its approved package inserts and/or Emergency Use Authorizations in the United States and in this District by others, including but not limited to healthcare providers and patients, and knowing that Comirnaty® is especially made or especially adapted for use to infringe the '493 patent, in violation of 35 U.S.C. § 271(c).

150. On information and belief, Counterclaim Defendants supply tozinameran and/or famtozinameran manufactured in the United States for formulation into Comirnaty® outside of the United States. On information and belief, Counterclaim Defendants have infringed or will infringe at least claims 1, 11, 13, 18, and 22 of the '493 patent, either literally or under the doctrine of

equivalents, in violation of 35 U.S.C. § 271(f), by supplying the global market for Comirnaty® with tozinameran and/or famtozinameran manufactured in the United States which constitutes a material part of the invention of at least claims 1, 11, 13, 18, and 22 of the '493 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use.

151. In July 2015, CureVac entered into a technology evaluation agreement with Acuitas Therapeutics Inc. ("Acuitas") under which CureVac evaluated certain lipid nanoparticle formulations to test their suitability as an mRNA delivery system. As part of CureVac's evaluation, CureVac conducted extensive studies regarding the safety and efficacy of various lipid nanoparticle formulations. As a result of those studies CureVac identified a single lipid nanoparticle candidate and conducted the first human clinical trial using an mRNA formulated in a lipid nanoparticle to study a rabies vaccine candidate. On January 7, 2020, CureVac issued a press release reporting that a vaccine containing the rabies mRNA formulated in a lipid nanoparticle "induced immune response in all subjects and was well tolerated." Exhibit 23 (CureVac Press Release) at Abstract. CureVac did not disclose the specific formulation used in that first-of-its-kind human rabies vaccine trial, or the results of CureVac's extensive development efforts that led to the selection of the lipid nanoparticle formulation used in that human trial. The lipid nanoparticle used in CureVac's human rabies vaccine trial is the same lipid nanoparticle recited in the '493 patent claims.

152. On information and belief, in 2017 Counterclaim Defendant BioNTech entered into a collaboration with Acuitas Therapeutics Inc. ("Acuitas") related to lipid nanoparticle technologies. Exhibit 24 (Acuitas Complaint) at ¶ 30. On information and belief, in January 2020, based on its knowledge of CureVac's unpublished confidential data establishing the safety and efficacy of an mRNA vaccine formulated with the specific lipid nanoparticle recited in the '493

patent claims in humans, Acuitas recommended to BioNTech that it use that same lipid nanoparticle CureVac used in its human rabies vaccine trial (and that is recited in the '493 patent claims) in formulating its COVID-19 vaccine. *Id.* On information and belief, prior to Acuitas's disclosure to BioNTech of CureVac's confidential proprietary results with the lipid nanoparticle recited in the '493 patent claims, Counterclaim Defendants' COVID-19 vaccine development program was utilizing a different lipid nanoparticle. Because Counterclaim Defendants received CureVac's confidential proprietary information from Acuitas regarding CureVac's success in formulating a safe and effective mRNA vaccine with the lipid nanoparticle recited in the '493 patent claims, Counterclaim Defendants copied the lipid nanoparticle formulation that CureVac showed was successful for use in Comirnaty®. Counterclaim Defendants' decision to copy the lipid nanoparticle formulation used by CureVac evinces a deliberate disregard for CureVac's patent rights. Counterclaim Defendants chose to advance BNT162b2 as their lead vaccine candidate knowing that it copied CureVac's formulation recited in the claims of the '493 patent. Counterclaim Defendants have continued to use the invention claimed in the '493 patent in deliberate disregard for CureVac's patent rights, including by using the invention in formulating Comirnaty® containing famtozinameran. Moreover, by at least March 29, 2022, BioNTech was provided with a presentation identifying 27 patents and patent applications in CureVac's patent portfolio, including the '493 patent. D.I. 47 at 12. Accordingly, Counterclaim Defendants' infringement of the '493 patent has been willful.

153. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of the '493 patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties for Counterclaim Defendants' infringement of the '493 patent.

154. Counterclaim Defendants have engaged in egregious infringement behavior with respect to the '493 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

155. Counterclaim Defendants' conduct with respect to the '493 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT VIII – INFRINGEMENT OF THE '525 PATENT

156. CureVac incorporates each of the above paragraphs 1–155 as though fully set forth herein.

157. The application that led to the issuance of the '525 patent was filed as a continuation of the same application to which the application that led to the '493 patent, and therefore the '525 patent shares a common specification with the '493 patent. The '525 patent is directed to methods of stimulating an immune response using an RNA-based vaccine composition that are directed to treating coronavirus infections, and in particular SARS-CoV-2 infections, by administering compositions that contain an mRNA that encodes a protein designed to mimic the shape of the pre-fusion form of the spike protein on the SARS-CoV-2 virus formulated in a lipid nanoparticle.

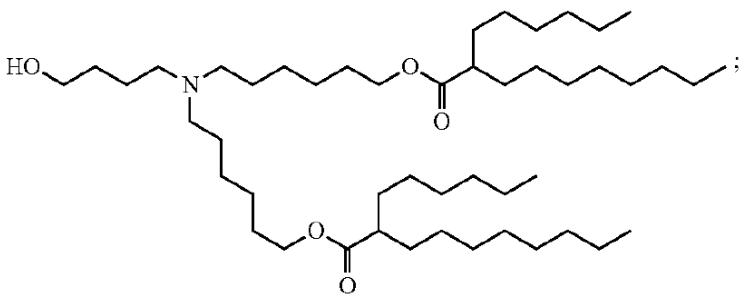
158. The '525 patent issued with 29 claims. Independent claim 1 recites:

> **1.** A method of stimulating an immune response in a subject, the method comprising administering to the subject an effective amount of a composition comprising:
>
> (I) a mRNA comprising:
>
> (a) at least one coding sequence which is at least 80% identical to SEQ ID NO: 137 encoding a severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) spike protein (S) at least 90% identical to SEQ ID NO: 10 that is a pre-fusion stabilized spike protein (S_stab) comprising a pre-fusion stabilizing K986P and V987P mutation and comprising a D614G amino acid substitution; and
>
> (b) a 5′ heterologous untranslated region (UTR) and a heterologous 3′ UTR, said heterologous 3′ UTR comprising a terminal poly(A) sequence of 30 to 200 adenosine nucleotides; and

(II) at least one pharmaceutically acceptable carrier, wherein the mRNA is complexed with lipid nanoparticles (LNP) and wherein the LNP comprise:

(i) at least one cationic lipid according to formula III-3:

(III-3)

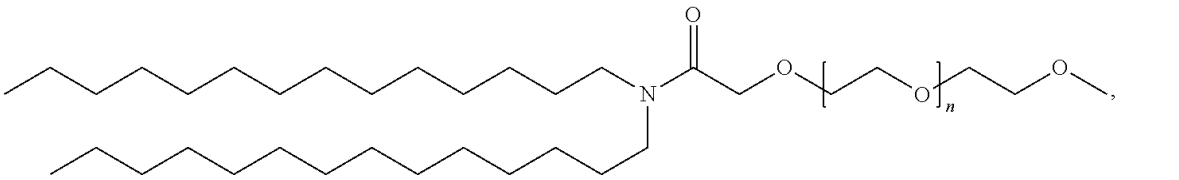


(ii) at least one neutral lipid, comprising 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC);

(iii) at least one steroid, comprising cholesterol; and

(iv) at least one polyethylene glycol (PEG)-lipid according to formula IVa:

IVa



wherein (i) to (iv) are in a molar ratio of about 20-60% cationic lipid, 5-25% neutral lipid, 25-55% sterol, and 0.5-5% PEG-lipid,

wherein the composition is administered by intramuscular injection.

159. Claims 2, 3, and 13 serially narrow claim 1:

2. The method of claim 1, wherein the mRNA comprises at least one coding sequence encoding a SARS-CoV-2 spike protein (S) at least 95% identical to SEQ ID NO: 10.

3. The method of claim 2, wherein the mRNA comprises a 5′-cap structure.

13. The method of claim 3, wherein the mRNA has been purified by a method comprising tangential flow filtration (TFF).

160. The use of Comirnaty® COVID-19 Vaccine, Bivalent as instructed in its package insert results in the stimulation of an immune response by administering the tozinameran and famtozinameran mRNA molecules, which contain the open reading frames encoding SARS CoV-2 viral spike protein antigens. *See* Press Release, Pfizer and BioNTech Granted FDA Emergency Use Authorization of Omicron BA.4/BA.5-Adapted Bivalent COVID-19 Vaccine Booster for Ages 12 Years and Older (Aug. 31, 2022), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-granted-fda-emergency-use-authorization (available in archival form at https://perma.cc/GL9T-U2GE) ("Clinical data from a Phase 2/3 trial showed a booster dose of Pfizer and BioNTech's Omicron BA.1-adapted bivalent vaccine elicited a superior immune response against the Omicron BA.1 subvariant compared to the companies' current COVID-19 vaccine, with a favorable safety profile").

161. Counterclaim Defendants' Comirnaty® COVID-19 Vaccine, Bivalent contains the famtozinameran mRNA molecule, which contains an open reading frame encoding the SARS CoV-2 viral spike protein antigen. Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("Codon-optimized sequences encoding the respective antigen of SARS-CoV-2 protein has following point mutations/deletions . . ."). On information and belief, famtozinameran has a coding sequence that is about 86% identical to SEQ ID NO: 137 in the '525 patent. The coding sequence of famtozinameran encodes a SARS-CoV-2 spike protein (S) that is about 97% identical to SEQ ID NO: 10 in the '525 patent, and contains pre-fusion stabilizing K986P and V987P mutations and a D614G amino acid substitution. *Id.* at 4 ("Codon-optimized sequences encoding the respective antigen of SARS-CoV-2 protein has following point mutations/deletions (reference for numbering Genbank ID QHD43416.1): T19I, ΔLPP24-26, A27S, ΔHV69-70, G142D, V213G, G339D, S371L, S373P, S375F, T376A, D405N, K417N, N440K, L452R,

S477N, T478K, E484A, F486V, Q498R, N501Y, Y505H, **D614G**, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K, **KV986-987PP**") (emphasis added).

162. On information and belief, Counterclaim Defendants' Comirnaty® COVID-19 Vaccine, Bivalent contains an mRNA (famtozinameran) that has a 5′-cap structure, and has 5′ and 3′ heterologous untranslated regions, the latter containing a terminal poly(A) comprising 70 adenosine residues. Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("**hAg-Kozak (nucleotides 1 to 53):** 5'-UTR sequence of the human alpha-globin mRNA with an optimized 'Kozak sequence' to increase translational efficiency"); *id.* at 2 ("A cap1 structure $m2^{7,3'\text{-}O}Gppp(m1^{2'\text{-}O})ApG$ is utilized as specific capping structure at the 5′-end of the RNA drug substance"); *id.* at 4 ("**A30L70 (nucleotides 4159 to 4268):** The circular plasmid, described in Section 3.2.S.2.3 Control of Materials – Source, History and Generation of Plasmids BNT162b2 [Omicron (BA.4/BA.5) Variant], provides a template for an mRNA transcript that contains two poly(A) tracts of 30 and approximately 70 adenosine residues joined by a linker") (emphases in original).

163. On information and belief, each 0.3 milliliter dose of Counterclaim Defendants' Comirnaty® COVID-19 Vaccine, Bivalent contains a combination of tozinameran and famtozinameran complexed with the following lipid nanoparticle components (i) ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) at a concentration of 7.17 mg/mL, which is the compound of formula III-3 recited in claim 1 and is also known as "ALC-0315"; (ii) 1,2-distearoylsn-glycero-3-phosphocholine at a concentration of 1.56 mg/mL, which is a neutral lipid; (iii) cholesterol at a concentration of 3.1 mg/mL; and (iv) 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, at a concentration of 0.89 mg/mL, which is a pegylated lipid of formula IVa recited in claim 1 and is also known as "ALC-0159." Exhibit 20 (Rapporteur Review)

at 113 (Table P.2-1). On information and belief, the components of the lipid nanoparticles in Comirnaty® are present in a molar ratio of cationic lipid:DSPC:cholesterol:PEG-lipid of approximately 47.5:10:40.7:1.8. *Id*. at 116 ("In vivo experiments after IM administration of the final ALC-0315/ALC-0159/DSPC/cholesterol LNP at molar ratio 47.5/10/40.7/1.8, confirmed expression of mRNA for this route of administration").

164. The package insert for Counterclaim Defendants' Comirnaty® COVID-19 Vaccine, Bivalent instructs a health care provider to administer a single 0.3 mL dose of Comirnaty® intramuscularly. Exhibit 13 (Comirnaty® Bivalent package insert) at 7 ("After withdrawing a single 0.3 mL dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent, administer immediately"); *id.* at 46 ("Pfizer-BioNTech COVID-19 Vaccine, Bivalent is a suspension for intramuscular injection").

165. On information and belief, the famtozinameran in Comirnaty® is transcribed from a linear DNA plasmid using an in vitro transcription (IVT) step followed by purification using tangential flow filtration ("TFF"). Exhibit 22 (EU Contract) at 61 (Manufacturing Process | In vitro transcription and tangential flow filtration (IVT/TFF)").

166. On information and belief, BioNTech Manufacturing is the holder of the FDA's Emergency Use Authorization for Counterclaim Defendants' Comirnaty® COVID-19 Vaccine, Bivalent. Exhibit 25 (Bivalent Letter) at 1. The use of Comirnaty® COVID-19 Vaccine, Bivalent as instructed by its package insert satisfies each and every element of at least claims 1–3 and 13 of the '525 patent. That package insert instructs medical professionals to administer Comirnaty® via an intramuscular injection. Exhibit 13 (Comirnaty® Bivalent package insert) at 2. Consequently, Counterclaim Defendants have induced infringement and continue to induce infringement of at least claims 1–3 and 13 of the '525 patent, either literally or under the doctrine

of equivalents, by encouraging healthcare providers to use Comirnaty® in the United States and in this District in a manner that would directly infringe the '525 patent. Indeed, the only use of Comirnaty® instructed in its package insert infringes the claims of the '525 patent. Counterclaim Defendants have intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '525 patent and with knowledge that their acts are encouraging infringement, in violation of 35 U.S.C. § 271(b).

167. On information and belief, Comirnaty® constitutes a material part of the invention of one or more claims of the '525 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Counterclaim Defendants have contributorily infringed and continue to contributorily infringe at least claims 1–3 and 13 of the '525 patent, either literally or under the doctrine of equivalents, by promoting the making and use of the Comirnaty® COVID-19 Vaccine, Bivalent in accordance with its Emergency Use Authorizations in the United States and in this District by healthcare providers, and knowing that Comirnaty® COVID-19 Vaccine, Bivalent is especially made or especially adapted for use to infringe the '525 patent in violation of 35 U.S.C. § 271(c).

168. On information and belief, Counterclaim Defendants had knowledge of the '525 patent and knowledge that their actions promoting the use of the Comirnaty® COVID-19 Vaccine, Bivalent in the United States induces infringement and contributorily infringes the '525 patent.

169. In July 2015, CureVac entered into a technology evaluation agreement with Acuitas Therapeutics Inc. ("Acuitas") under which CureVac evaluated certain lipid nanoparticle formulations to test their suitability as an mRNA delivery system. As part of CureVac's evaluation, CureVac conducted extensive studies regarding the safety and efficacy of various lipid

nanoparticle formulations. As a result of those studies CureVac identified a single lipid nanoparticle candidate and conducted the first human clinical trial using an mRNA formulated in a lipid nanoparticle to study a rabies vaccine candidate. On January 7, 2020, CureVac issued a press released reporting that vaccine containing the rabies mRNA formulated in a lipid nanoparticle "induced immune response in all subjects and was well tolerated." Exhibit 23 (CureVac Press Release) at Abstract. CureVac did not disclose the specific formulation used in that first-of-its-kind human rabies vaccine trial, or the results of CureVac's extensive development efforts that led to the selection of the lipid nanoparticle formulation used in that human trial. The lipid nanoparticle used in CureVac's human rabies vaccine trial is the same lipid nanoparticle recited in the '525 patent claims.

170. On information and belief, in 2017 Counterclaim Defendant BioNTech entered into a collaboration with Acuitas Therapeutics Inc. ("Acuitas") related to lipid nanoparticle technologies. Exhibit 24 (Acuitas Complaint) at ¶ 30. On information and belief, in January 2020, based on its knowledge of CureVac's unpublished confidential data establishing the safety and efficacy of an mRNA vaccine formulated with the specific lipid nanoparticle recited in the '525 patent claims in humans, Acuitas recommended to BioNTech that it use that same lipid nanoparticle CureVac used in its human rabies vaccine trial (and that is recited in the '525 patent claims) in formulating its COVID-19 vaccine. *Id.* On information and belief, prior to Acuitas's disclosure of CureVac's confidential proprietary results with the lipid nanoparticle recited in the '525 patent claims to BioNTech, Counterclaim Defendants' COVID-19 vaccine development program was utilizing a different lipid nanoparticle. Because Counterclaim Defendants received CureVac's confidential proprietary information from Acuitas regarding CureVac's success in formulating a safe and effective mRNA vaccine with the lipid nanoparticle recited in the '525

patent claims, Counterclaim Defendants copied the lipid nanoparticle formulation that was brought to the clinic by CureVac for use in Comirnaty®. Counterclaim Defendants' decision to copy CureVac's the lipid nanoparticle formulation evinces a deliberate disregard for CureVac's patent rights. Counterclaim Defendants chose to advance BNT162b2 as their lead vaccine candidate knowing that it comprises the components copied from CureVac's formulation and recited in the claims of the '525 patent. Counterclaim Defendants have continued to use the invention claimed in the '525 patent in deliberate disregard for CureVac's patent rights, including by using the invention in formulating Comirnaty® containing famtozinameran. Moreover, by at least April 7, 2022, BioNTech was provided with a presentation identifying 37 patents and patent applications in CureVac's patent portfolio, including the application that led to the issuance of the '525 patent. D.I. 47 at 12. Accordingly, Counterclaim Defendants' infringement of the '525 patent has been willful.

171. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of the '525 patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties for Counterclaim Defendants' infringement of the '525 patent.

172. Counterclaim Defendants have engaged in egregious infringement behavior with respect to the '525 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

173. Counterclaim Defendants' conduct with respect to the '525 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT IX – INFRINGEMENT OF THE '966 PATENT

174. CureVac incorporates each of the above paragraphs 1–173 as though fully set forth herein.

175. The application that led to the issuance of the '966 patent was filed as a continuation of the same application that led to the '493 and '525 patents, and therefore the '966 patent shares

a common specification with the '493 and '525 patents. The '966 patent is directed to RNA-based vaccine compositions for treating coronavirus infections, in particular SARS-CoV-2 infections, containing an mRNA that encodes a protein designed to mimic the shape of the pre-fusion form of the spike protein on the SARS-CoV-2 virus, and has additional mutations. The '966 patent also describes formulating the mRNA in a lipid nanoparticle ("LNP") containing at least one cationic lipid, at least one neutral lipid, at least one steroid or steroid analog, preferably cholesterol, and at least one polymer conjugated lipid, preferably a polyethylene glycol-lipid.

176. The '966 patent issued with 27 claims. Independent claim 1 recites:

> **1.** A composition comprising a mRNA comprising:
>
> (a) at least one coding sequence encoding a SARS-CoV-2 spike protein (S) at least 95% identical to SEQ ID NO: 10 that is a pre-fusion stabilized spike protein (S_stab) comprising K986P and V987P stabilizing mutations and H69del, V70del, S477N, T478K, E484A, N501Y, and D614G amino acid substitutions relative to SEQ ID NO: 10;
>
> (b) at least one heterologous untranslated region (UTR); and
>
> (c) at least one pharmaceutically acceptable carrier, wherein the mRNA is complexed or associated with lipid nanoparticles (LNP) and wherein the LNP comprises:
>
> (i) at least one cationic lipid;
>
> (ii) at least one neutral lipid;
>
> (iii) at least one steroid or steroid analogue; and
>
> (iv) at least one PEG-lipid,
>
> wherein (i) to (iv) are in a molar ratio of about 20-60% cationic lipid, 5-25% neutral lipid, 25-55% sterol, and 0.5-10% PEG-lipid.

177. Claims 4, 11, and 14 narrow claim 1:

> **4.** The composition of claim 1, wherein the at least one coding sequence of the mRNA has a G/C content of at least about 50%.
>
> **11.** The composition of claim 1, wherein the mRNA is a purified mRNA that has been purified by RP-HPLC and/or TFF.

14. The composition of claim 1, wherein at least 80% of the mRNA is intact at least about two weeks after storage as a liquid at temperatures of about 5° C.

178. Counterclaim Defendants' Comirnaty® COVID-19 Vaccine, Bivalent contains the famtozinameran mRNA molecule, which contains an open reading frame (ORF) encoding the SARS CoV-2 viral spike protein antigen. Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("Codon-optimized sequences encoding the respective antigen of SARS-CoV-2 protein has following point mutations/deletions . . ."). On information and belief, famtozinameran has a coding sequence that encodes a SARS-CoV-2 spike protein (S) that is about 97% identical to SEQ ID NO: 10 in the '525 patent, and contains the pre-fusion stabilizing K986P and V987P mutations, and has the following amino acid substitutions relative to SEQ ID NO: 10: H69del, V70del, S477N, T478K, E484A, N501Y, and D614G. *Id.* at 4 ("Codon-optimized sequences encoding the respective antigen of SARS-CoV-2 protein has following point mutations/deletions (reference for numbering Genbank ID QHD43416.1): T19I, ΔLPP24-26, A27S, **ΔHV69-70**, G142D, V213G, G339D, S371L, S373P, S375F, T376A, D405N, K417N, N440K, L452R, **S477N**, **T478K**, **E484A**, F486V, Q498R, **N501Y**, Y505H, **D614G**, H655Y, N679K, P681H, N764K, D796Y, Q954H, N969K, **KV986-987PP**") (emphasis added).

179. On information and belief, the mRNA in Comirnaty® contains at least one heterologous untranslated region: the 5′-untranslated region derived from human alpha-globin RNA with an optimized Kozak sequence. Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("**hAg-Kozak (nucleotides 1 to 53):** 5'-UTR sequence of the human alpha-globin mRNA with an optimized 'Kozak sequence' to increase translational efficiency").

180. On information and belief, each 0.3 milliliter dose of Counterclaim Defendants' Comirnaty® COVID-19 Vaccine, Bivalent contains a combination of tozinameran and famtozinameran complexed with the following lipid nanoparticle components (i) ((4-

hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) at a concentration of 7.17 mg/mL, which is the compound of formula III-3 recited in claim 1 and is also known as "ALC-0315"; (ii) 1,2-distearoylsn-glycero-3-phosphocholine at a concentration of 1.56 mg/mL, which is a neutral lipid; (iii) cholesterol at a concentration of 3.1 mg/mL; and (iv) 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, at a concentration of 0.89 mg/mL, which is a pegylated lipid of formula IVa recited in claim 1 and is also known as "ALC-0159." Exhibit 20 (Rapporteur Review) at 113 (Table P.2-1). On information and belief, the components of the lipid nanoparticles in Comirnaty® are present in a molar ratio of cationic lipid:DSPC:cholesterol:PEG-lipid of approximately 47.5:10:40.7:1.8. *Id*. at 116 ("In vivo experiments after IM administration of the final ALC-0315/ALC-0159/DSPC/cholesterol LNP at molar ratio 47.5/10/40.7/1.8, confirmed expression of mRNA for this route of administration").

181. On information and belief, the coding sequence of famtozinameran has a G/C content of about 57%. *See* Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 5–6.

182. On information and belief, famtozinameran is transcribed from a linear DNA plasmid using an in vitro transcription (IVT) step followed by purification using tangential flow filtration ("TFF"). Exhibit 22 (EU Contract) at 61 (Manufacturing Process | In vitro transcription and tangential flow filtration (IVT/TFF)").

183. On information and belief, the famtozinameran in Counterclaim Defendants' Comirnaty® COVID-19 Vaccine, Bivalent is at least 80% intact at least about two weeks after storage as a liquid at temperatures of about 5° C. Exhibit 20 (Rapporteur Review) at 184 ("At accelerated conditions of +5°C-storage and up to 4 months testing of a clinical batch of drug

product, LNP polydispersity and RNA integrity were out of specification at the 3 and 4 month-points").

184. Thus, on information and belief, Counterclaim Defendants' Comirnaty® COVID-19 Vaccine, Bivalent satisfies all of the limitations of at least claims 1, 4, 11, and 14 of the '966 patent for all of the reasons described above.

185. On information and belief, Counterclaim Defendants have directly infringed and continue to directly infringe at least claims 1, 4, 11, and 14 of the '966 patent, either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing Counterclaim Defendants' Comirnaty® COVID-19 Vaccine, Bivalent in the United States and in this District without authority, in violation of 35 U.S.C. § 271(a).

186. On information and belief, Counterclaim Defendants have induced infringement and continue to induce infringement of at least claims 1, 4, 11, and 14 of the '966 patent, either literally or under the doctrine of equivalents, by encouraging others, including but not limited to healthcare providers and patients, to use Counterclaim Defendants' Comirnaty® COVID-19 Vaccine, Bivalent in the United States and in this District in a manner that would directly infringe the '966 patent. Counterclaim Defendants have intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '966 patent and with knowledge that their acts are encouraging infringement, in violation of 35 U.S.C. § 271(b).

187. On information and belief, Comirnaty® constitutes a material part of the invention of at least claims 1, 4, 11, and 14 of the '966 patent and is not a staple article or commodity of commerce suitable for substantial non-infringing use. Counterclaim Defendants have contributorily infringed and continue to contributorily infringe at least claims 1, 4, 11, and 14 of

the '966 patent, either literally or under the doctrine of equivalents, by promoting the use of Counterclaim Defendants' Comirnaty® COVID-19 Vaccine, Bivalent in accordance with its Emergency Use Authorization in the United States and in this District by others, including but not limited to healthcare providers and patients, and knowing that Comirnaty® is especially made or especially adapted for use to infringe the '966 patent, in violation of 35 U.S.C. § 271(c).

188. On information and belief, Counterclaim Defendants had knowledge of the '966 patent and knowledge that their actions promoting the use of Counterclaim Defendants' Comirnaty® COVID-19 Vaccine, Bivalent in the United States induces infringement and contributorily infringes the '966 patent.

189. Counterclaim Defendants have continued to use the invention claimed in the '966 patent in deliberate disregard for CureVac's patent rights, including by using the invention in formulating Comirnaty® containing famtozinameran. Moreover, by at least April 7, 2022, BioNTech was provided with a presentation identifying 37 patents and patent applications in CureVac's patent portfolio, including the application that led to the issuance of the '966 patent. D.I. 47 at 12. Accordingly, Counterclaim Defendants' infringement of the '966 patent has thus been willful.

190. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of the '966 patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties for Counterclaim Defendants' infringement of the '966 patent.

191. Counterclaim Defendants have engaged in egregious infringement behavior with respect to the '966 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

192. Counterclaim Defendants' conduct with respect to the '966 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT X – INFRINGEMENT OF THE ’686 PATENT

193. CureVac incorporates each of the above paragraphs 1–192 as though fully set forth herein.

194. The application that led to the issuance of the ’686 patent was filed as a continuation of the application that led to the ’493, ’525, and ’966 patents, and therefore the ’686 patent shares a common specification with the ’493, ’525, and ’966 patents. The ’686 patent is directed to purified mRNAs that encode a protein designed to mimic the shape of the pre-fusion form of the spike protein on the SARS-CoV-2 virus, as well as additional mutations. The ’686 patent also describes formulating the mRNA in a lipid nanoparticle (“LNP”) containing at least one cationic lipid, at least one neutral lipid, at least one steroid or steroid analog, preferably cholesterol, and at least one polyethylene glycol (PEG)-lipid.

195. The ’686 patent issued with 30 claims. Independent claim 26 recites:

> **26.** A composition comprising:
>
> (I) a purified mRNA comprising:
>
> (a) a 5' cap structure;
>
> (b) a heterologous 5' untranslated region (UTR);
>
> (c) a coding sequence encoding a SARS-CoV-2 spike protein (S) at least 95% identical to SEQ ID NO: 10 that is a pre-fusion stabilized spike protein (S_stab) comprising K986P and V987P stabilizing substitutions and further comprising a D614G amino acid substitution relative to SEQ ID NO: 10; and
>
> (d) a heterologous 3' UTR, comprising a terminal poly(A) sequence of 30 to 200 adenosine nucleotides,
>
> wherein 100% of the uracil positions in the mRNA are replaced with 1-methylpseudouridine; and
>
> (II) at least one pharmaceutically acceptable carrier,
>
> wherein the mRNA is complexed or associated with lipid nanoparticles (LNPs).

196. Claim 27 narrows claim 26:

> **27.** The composition of claim 26, wherein the LNPs comprises:
>
> (i) at least one cationic lipid;
>
> (ii) at least one neutral lipid;
>
> (iii) at least one steroid or steroid analogue; and
>
> (iv) at least one PEG-lipid,
>
> wherein (i) to (iv) are in a molar ratio of about 20-60% cationic lipid, 5-25% neutral lipid, 25-55% sterol, and 0.5-5% PEG-lipid.

197. Claim 30 is directed to a method of stimulating an immune response, and recites:

> **30.** A method of stimulating an immune response to a coronavirus spike protein in a subject comprising administering to the subject an effective amount of a composition according to claim 27.

198. Counterclaim Defendants' Comirnaty® COVID-19 Vaccine, Bivalent contains the famtozinameran mRNA molecule, which contains an open reading frame encoding the SARS CoV-2 viral spike protein antigen. Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 4 ("Codon-optimized sequences encoding the respective antigen of SARS-CoV-2 protein has following point mutations/deletions . . ."). On information and belief, famtozinameran has a coding sequence that encodes a SARS-CoV-2 spike protein (S) that is about 97% identical to SEQ ID NO: 10 in the '686 patent, and contains the pre-fusion stabilizing K986P and V987P mutations and the D614G amino-acid substitution relative to SEQ ID NO: 10. *Id.* at 4 ("Codon-optimized sequences encoding the respective antigen of SARS-CoV-2 protein has following point mutations/deletions (reference for numbering Genbank ID QHD43416.1): . . . **D614G** . . . **KV986-987PP**") (emphasis added).

199. The famtozinameran mRNA molecule in the bivalent version of Comirnaty® contains a "cap" at the 5' end of the molecule. Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 6 ("Sequence length: 4269, which includes 'Cap-' to denote the presence

of the 5'-cap analog"). The famtozinameran mRNA molecule in the bivalent version of Comirnaty® contains at least one heterologous 5' untranslated region, the 5'-untranslated region derived from human alpha-globin RNA with an optimized Kozak sequence. *Id.* at 4 ("**hAg-Kozak (nucleotides 1 to 53):** 5'-UTR sequence of the human alpha-globin mRNA with an optimized 'Kozak sequence' to increase translational efficiency"), and at least one 3' untranslated region that contains a "110-nucleotide poly(A)-tail consisting of a stretch of 30 adenosine residues, followed by a 10-nucleotide linker sequence and another 70 adenosine residues. *Id.* (emphasis in original).

200. On information and belief, when the famtozinameran mRNA molecule in the bivalent version of Comirnaty® is transcribed from its plasmid, a modified form of uridine, 1-methyl-3'-pseudouridylyl, is incorporated at the positions that would otherwise contain uridine residues. Exhibit 15 (Sec. 3.2.S.1.2 Structure [Omicron (BA.4/BA.5) Variant]) at 3.

201. On information and belief, each 0.3 milliliter dose of Counterclaim Defendants' Comirnaty® COVID-19 Vaccine, Bivalent contains a combination of tozinameran and famtozinameran complexed with the following lipid nanoparticle components (i) ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), which is a cationic lipid, at a concentration of 7.17 mg/mL; (ii) 1,2-distearoylsn-glycero-3-phosphocholine, which is a neutral lipid, at a concentration of 1.56 mg/mL; (iii) cholesterol, which is a steroid, at a concentration of 3.1 mg/mL; and (iv) 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, which is a pegylated (PEG)-lipid known as PEG-2000-DMG, at a concentration of 0.89 mg/mL. Exhibit 20 (Rapporteur Review) at 113 (Table P.2-1). On information and belief, the components of the lipid nanoparticles in Comirnaty® are present in a molar ratio of 47.5% cationic lipid, 10% DSPC, 40.7% cholesterol, and 1.8% PEG-lipid. *Id.* at 116 ("In vivo experiments after IM administration

of the final ALC-0315/ALC-0159/DSPC/cholesterol LNP at molar ratio 47.5/10/40.7/1.8, confirmed expression of mRNA for this route of administration").

202. On information and belief, Counterclaim Defendants have directly infringed and continue to directly infringe at least claims 26 and 27 of the '686 patent, either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing Counterclaim Defendants' Comirnaty® COVID-19 Vaccine, Bivalent in the United States and in this District without authority, in violation of 35 U.S.C. § 271(a).

203. On information and belief, BioNTech Manufacturing is the holder of the FDA's Emergency Use Authorization for Comirnaty®. Exhibit 25 (Bivalent Letter) at 1. Use of Comirnaty® as instructed by Counterclaim Defendants in their package insert satisfies each and every element of at least claim 30 of the '686 patent: the package insert instructs medical professionals to administer Comirnaty® via an intramuscular injection, and thereby stimulate an immune response to a coronavirus spike protein. Exhibit 13 (Comirnaty® Bivalent package insert) at 2.

204. Thus, on information and belief, Comirnaty® satisfies all of the limitations of at least claims 26, 27, and 30 in the '686 patent for all of the reasons described above.

205. On information and belief, Counterclaim Defendants have directly infringed and continue to directly infringe at least claims 26 and 27 in the '686 patent, either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing Pfizer-BioNTech's Comirnaty® COVID-19 Vaccine, Bivalent in the United States and in this District without authority, in violation of 35 U.S.C. § 271(a).

206. On information and belief, Counterclaim Defendants have induced infringement and continue to induce infringement of at least claim 30 in the '686 patent, either literally or under

the doctrine of equivalents, by encouraging others, including but not limited to healthcare providers and patients, to use Comirnaty® in the United States and in this District in a manner that would directly infringe the '686 patent. Counterclaim Defendants have intentionally encouraged and will continue to intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '686 patent and with knowledge that their acts are encouraging infringement, in violation of 35 U.S.C. § 271(b).

207. On information and belief, Comirnaty® constitutes a material part of the invention of one or more claims in the '686 patent and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Counterclaim Defendants have contributorily infringed and continue to contributorily infringe at least claim 30 in the '686 patent, either literally or under the doctrine of equivalents, by promoting the use of Counterclaim Defendants' Comirnaty® COVID-19 Vaccine, Bivalent in accordance with its Emergency Use Authorization in the United States and in this District by others, including but not limited to healthcare providers and patients, and knowing that Comirnaty® is especially made or especially adapted for use to infringe the '686 patent, in violation of 35 U.S.C. § 271(c).

208. On information and belief, Counterclaim Defendants had knowledge of the '686 patent and knowledge that their actions promoting the use of Counterclaim Defendants' Comirnaty® COVID-19 Vaccine, Bivalent in the United States induces infringement and contributorily infringes the '686 patent.

209. Counterclaim Defendants have continued to use the invention claimed in the '686 patent in deliberate disregard for CureVac's patent rights, including by using the invention in formulating Comirnaty® containing famtozinameran. Accordingly, Counterclaim Defendants' infringement of the '686 patent has thus been willful.

210. CureVac has suffered damages as a result of Counterclaim Defendants' infringement of the '686 patent. CureVac is entitled to an award of compensatory damages, including reasonable royalties for Counterclaim Defendants' infringement of the '686 patent.

211. Counterclaim Defendants have engaged in egregious infringement behavior with respect to the '686 patent warranting an award of enhanced damages pursuant to 35 U.S.C. § 284.

212. Counterclaim Defendants' conduct with respect to the '686 patent makes this case stand out from others and warrants an award of attorneys' fees pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, CureVac prays that this Court grant the following relief:

a. A judgment that Counterclaim Defendants have infringed one or more claims of '312, '278, '492, '920, '070,'493, '525, '966, and '686 patents, induced infringement of one or more claims of the '312, '278, '492, '920, '070, '493, '525, '966, and '686 patents, and/or contributorily infringed one of more claims of the '312, '278, '492, '920, '070, '493, '966, and '686 patents;

b. A judgment that Counterclaim Defendants have infringed the '312 patent under 35 U.S.C. § 154(d);

c. A judgment that Counterclaim Defendants' infringement has been and is willful;

d. An award to CureVac of monetary damages for Counterclaim Defendants' infringement, including reasonable royalties, together with interest, costs, expenses, disbursements, and an accounting and/or ongoing royalty for any post-judgment infringement;

e. An award to CureVac of all other damages permitted by 35 U.S.C. § 284, including enhanced damages up to three times the amount of compensatory damages found;

f. A declaration that this is an exceptional case and an award to CureVac of its attorneys' fees, costs, and expenses, pursuant to 35 U.S.C. § 285; and

g. Such other relief as this Court may deem just and proper, except CureVac does not seek injunctive relief against Comirnaty®(tozinameran) and Comirnaty® COVID-19 Vaccine, Bivalent.

DEMAND FOR JURY TRIAL

CureVac requests a trial by jury on all issues so triable in accordance with Rule 38 of the Federal Rules of Civil Procedure.

* * *

ANSWER

Defendant CureVac SE ("CureVac") hereby respond to Plaintiffs BioNTech SE, BioNTech Manufacturing GmbH (collectively the BioNTech entities are referred to herein as "BioNTech"), and Pfizer, Inc. ("Pfizer") (collectively "Plaintiffs") Complaint as follows:

INTRODUCTION

1. This is an action brought by BioNTech and Pfizer who partnered together, and continue to work together, to address the greatest public health threat the United States and the world has faced in at least a century: the COVID-19 pandemic. Now, BioNTech and Pfizer must also face threats of a groundless patent infringement suit by a company, CureVac, who has been unable to bring to market any product to help in the fight against COVID-19.

ANSWER: CureVac admits that the COVID-19 pandemic is one of the greatest public health threats the United States and the world have faced in at least a century. CureVac denies the remaining allegations in Paragraph 1.

2. BioNTech and Pfizer partnered together to develop, manufacture, and secure regulatory approval for a vaccine that proved to be effective in preventing severe disease, hospitalization, and death from COVID-19 infection. BioNTech and Pfizer did so at great risk to their companies, by investing considerable sums of money and countless hours in an effort to address this global pandemic. BioNTech and Pfizer successfully developed a product, proved its efficacy, established global manufacturing and supply chains, and gained regulatory approval in record time. Through their efforts they were able to help the United States and the world begin to move past the COVID-19 public health crisis.

ANSWER: CureVac admits that BioNTech secured regulatory approval for a vaccine that proved to be effective in preventing severe disease, hospitalization, and death from COVID-19 infection. CureVac denies the remaining allegations in Paragraph 2.

3. Unlike BioNTech's and Pfizer's efforts, CureVac's failed, as it was unable to develop a COVID-19 vaccine product. After this failure, CureVac turned its attention to an attempt to profit from the success of BioNTech and Pfizer through threats of patent infringement.

ANSWER: CureVac denies the allegations in Paragraph 3.

4. BioNTech and Pfizer bring this action to resolve CureVac's meritless allegations.

ANSWER: CureVac denies the allegations in Paragraph 4.

NATURE OF THE ACTION

5. This is a civil action for a declaratory judgment that U.S. Patent Nos. 11,135,312, 11,149,278, and 11,241,493 (collectively, "the patents-in-suit" and attached as Exhibits 1 to 3 of this Complaint) are not infringed by the manufacture, use, offer to sell, and sale in the United States, and the importation into the United States, of the mRNA vaccine against COVID-19 that BioNTech created and made available to doctors and patients with Pfizer.

ANSWER: Insofar as Paragraph 5 contains legal conclusions, no response is required. To the extent a response is required, CureVac admits that Plaintiffs' Complaint purports to be an action for a declaratory judgment that U.S. Patent Nos. 11,135,312, 11,149,278, and 11,241,493 are not infringed. CureVac denies the remaining allegations in Paragraph 5.

6. This action arises under the Declaratory Judgment Act, 28 U.S.C. § 2201 and the patent laws of the United States, including Title 35, United States Code.

ANSWER: Insofar as Paragraph 6 contains legal conclusions, no response is required. To the extent a response is required, CureVac admits that Plaintiffs' Complaint purports to be an action under the Declaratory Judgment Act and the patent laws of the United States, including Title 35, United States Code. CureVac denies the remaining allegations in Paragraph 6.

THE PARTIES

7. Plaintiff BioNTech SE is a company organized and existing under the laws of Germany, having a principal place of business at An der Goldgrube 12, D-55131 Mainz, Germany.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 7 and therefore denies them.

8. Plaintiff BioNTech Manufacturing is a company organized and existing under the laws of Germany, having a principal place of business at An der Goldgrube 12, D-55131 Mainz, Germany.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 8 and therefore denies them.

9. BioNTech Manufacturing is a wholly owned subsidiary of BioNTech SE.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 9 and therefore denies them.

10. Plaintiff Pfizer is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 235 East 42nd Street, New York, New York 10017.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 10 and therefore denies them.

11. Upon information and belief, Defendant CureVac is a company organized and existing under the laws of Germany, having a place of business at Friedrich-Miescher-Straße 15, 72076 Tübingen, Germany.

ANSWER: In so far as the allegation is directed to CureVac SE, CureVac denies the allegations in Paragraph 11. As set forth in Paragraph 7 of CureVac's Counterclaims, CureVac SE merged with CureVac Beteiligungsverwaltungs AG on September 2022, and changed its name to CureVac SE. CureVac admits that CureVac SE is a company organized and existing under the laws of Germany, having a place of business at Friedrich-Miescher-Straße 15, 72076 Tübingen, Germany.

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), and 2201.

ANSWER: Insofar as Paragraph 12 contains legal conclusions, no response is required. To the extent that a response is required, CureVac does not contest that the Court has subject matter jurisdiction over this action.

13. As described in detail below, an actual, immediate, substantial, and justiciable controversy exists between Plaintiffs and CureVac as to whether the Pfizer-BioNTech COVID-19 vaccine (sold commercially as "COMIRNATY® vaccine") has infringed or will infringe the patents-in-suit.

ANSWER: Insofar as Paragraph 13 contains legal conclusions, no response is required. To the extent that a response is required, CureVac admits that a justiciable controversy exists between Plaintiffs and CureVac.

14. This Court has personal jurisdiction over CureVac under Fed. R. Civ. P. 4(k)(2).

ANSWER: Insofar as Paragraph 14 contains legal conclusions, no response is required. To the extent that a response is required, CureVac does not contest the Court has personal jurisdiction over CureVac for purposes of this action only. CureVac denies the remaining allegations in Paragraph 14.

15. This Court also has personal jurisdiction over CureVac, because, *inter alia*, upon information and belief, CureVac: (1) maintains pervasive, continuous, and systematic contacts with Massachusetts; (2) conducts business in Massachusetts through its office and agents located in Massachusetts; (3) sends agents into Massachusetts on a regular basis to conduct business; and (4) holds itself out as doing business in Massachusetts.

ANSWER: Insofar as Paragraph 15 contains legal conclusions, no response is required. To the extent that a response is required, CureVac does not contest this Court has personal jurisdiction over CureVac for purposes of this action only. CureVac denies the remaining allegations in Paragraph 15.

16. Upon information and belief, since at least November 2017, CureVac has entered into agreements and conducted business with multiple entities located in Massachusetts.

ANSWER: CureVac admits that it entered into sponsored research agreements with two entities located in Massachusetts. CureVac denies the remaining allegations in Paragraph 16.

17. Upon information and belief, in 2020, in connection with its initial public offering, (a) CureVac N.V. was incorporated and became the holding company of CureVac and (b) the historical consolidated financial statements of CureVac became part of the historical consolidated financial statements of CureVac N.V. (Exhibit 4.)

ANSWER: Insofar as Paragraph 17 contains legal conclusions, no response is required. To the extent that a response is required, CureVac admits that Exhibit 4 states:

> On April 7, 2020, CureVac B.V. was incorporated under the laws of the Netherlands and became the holding company of CureVac AG in connection with our initial public offering on August 14, 2020, pursuant to the Corporate Reorganization. As part of the Corporate Reorganization, the legal form of CureVac B.V. was converted from a Dutch private company with limited liability (besloten vennootschap met beperkte aansprakelijkheid) to a Dutch public company (naamloze vennootschap), and the articles of association of CureVac N.V. became effective. Following the Corporate Reorganization, CureVac N.V. became the holding company of CureVac AG and the historical consolidated financial statements of CureVac AG included in this Annual Report became part of the historical consolidated financial statements of CureVac N.V. Our legal and commercial name is CureVac N.V.

CureVac denies the remaining allegations in Paragraph 17.

18. Upon information and belief, CureVac is a wholly owned subsidiary of CureVac N.V.

ANSWER: CureVac denies the allegations in Paragraph 18.

19. Upon information and belief, CureVac also conducts business in Massachusetts, *inter alia*, through its wholly owned subsidiary CureVac, Inc.

ANSWER: CureVac denies the allegations in Paragraph 19.

20. Upon information and belief, CureVac, Inc. acts as an agent for CureVac for conducting business in the United States, including Massachusetts.

ANSWER: Insofar as Paragraph 20 contains legal conclusions, no response is required. To the extent that a response is required, CureVac denies the allegations in Paragraph 20.

21. Upon information and belief, CureVac N.V. has designated CureVac, Inc. as its agent for service of process in the United States.

ANSWER: CureVac admits the allegations in Paragraph 21.

22. Upon information and belief, CureVac, Inc. maintains a lease on a property of more than 12,000 square feet at 250 Summer Street, 3rd Floor, Boston, Massachusetts 02210.

ANSWER: CureVac admits the allegations in Paragraph 22.

23. Upon information and belief, CureVac, Inc. is registered with the Commonwealth of Massachusetts as a business in Massachusetts.

ANSWER: CureVac admits the allegations in Paragraph 23.

24. Upon information and belief, the Foreign Corporation Certificate of Registration filed by CureVac, Inc. with the Commonwealth of Massachusetts lists the CEO of CureVac as a corporate officer and director of CureVac, Inc.

ANSWER: CureVac admits the allegations in Paragraph 24.

25. Upon information and belief, CureVac sends employees and agents into Massachusetts, including to CureVac, Inc.'s office located at 250 Summer Street, 3rd Floor, Boston, Massachusetts 02210, on a regular basis.

ANSWER: CureVac admits that members of CureVac AG Executive Board were sent to Massachusetts six times in the last four years. CureVac denies the remaining allegations in Paragraph 25.

26. Upon information and belief, CureVac lists Boston, USA as one of its offices. For example, CureVac holds itself out as a "Tübingen, Germany/Boston, MA, USA" entity, *inter alia*, on its corporate website and in press releases. CureVac has also stated that it "employs more than 900 people at its sites in Tübingen, Frankfurt, and Boston, USA." (Exhibit 20.)

ANSWER: CureVac admits that Exhibit 20 to the Complaint contains the text "Tübingen, Germany/Boston, MA, USA" and "employs more than 900 people at its sites in

Tübingen, Frankfurt, and Boston, USA." CureVac denies the remaining allegations in Paragraph 26.

27. This Court also has personal jurisdiction over CureVac because, *inter alia*, it sent communications regarding CureVac's assertion of intellectual property ("IP") rights in connection with COMIRNATY® vaccine to individuals at BioNTech US Inc., which is located in Cambridge, Massachusetts.

ANSWER: Insofar as Paragraph 27 contains legal conclusions, no response is required. To the extent that a response is required, CureVac denies the allegations in Paragraph 27.

28. This Court also has personal jurisdiction over CureVac because, *inter alia*, the group of representatives who were involved in CureVac's assertion of IP rights in connection with COMIRNATY® vaccine included the Director IP Management US of CureVac, Inc., which is located in Boston, Massachusetts.

ANSWER: Insofar as Paragraph 28 contains legal conclusions, no response is required. To the extent that a response is required, CureVac denies the allegations in Paragraph 28.

29. This Court has personal jurisdiction over CureVac for at least the reasons set forth above and for other reasons that will be presented to the Court if such personal jurisdiction were to be challenged.

ANSWER: Insofar as Paragraph 29 contains legal conclusions, no response is required. To the extent that a response is required, CureVac denies the allegations in Paragraph 29.

30. Venue is proper in this Court under 28 U.S.C. §§ 1391(c)(3) and 1400(b) because CureVac is a foreign corporation and is subject to this Court's personal jurisdiction for at least the reasons set forth above.

ANSWER: Insofar as Paragraph 30 contains legal conclusions, no response is required. To the extent that a response is required, CureVac does not contest that venue is proper in this district for purposes of this action only.

31. Venue is proper for at least the reasons set forth above and for other reasons that will be presented to the Court if such venue were to be challenged.

ANSWER: Insofar as Paragraph 31 contains legal conclusions, no response is required. To the extent that a response is required, CureVac does not contest that venue is proper in this district for purposes of this action only.

32. This Court is authorized to issue declaratory judgments pursuant to 28 U.S.C. § 2201.

ANSWER: CureVac admits the allegations in Paragraph 32.

BACKGROUND

BioNTech

33. BioNTech SE is a global biotechnology company specializing in the development of novel medicines. BioNTech SE scientists have been researching and developing proprietary mRNA-based technologies for more than 20 years, achieving expertise in, *inter alia*, translational drug discovery and development, GMP manufacturing, and commercial capabilities.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 33 and therefore denies them.

34. BioNTech SE has been using its proprietary technologies across multiple technology platforms—including not only mRNA vaccines, but also small molecules, protein therapeutics, and other cell and gene therapies—to address human diseases with unmet medical need and major health burdens, such as cancer and infectious disease.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 34 and therefore denies them.

35. Since its foundation, BioNTech SE has worked on mRNA-based vaccine candidates, earning itself a reputation as an industry leader in mRNA technology. BioNTech partnered with several companies and research institutes to develop mRNA-based vaccines.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 35 and therefore denies them.

36. BioNTech Manufacturing is the holder of Biologics License Application No. 125742 for COMIRNATY® vaccine.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 36 and therefore denies them.

Pfizer

37. Pfizer Inc. is a research-based biopharmaceutical company. Pfizer applies science and its global resources to bring therapies to people that extend and significantly improve their lives through the discovery, development, manufacture, marketing, sale, and distribution of biopharmaceutical products.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 37 and therefore denies them.

38. Pfizer works across developed and emerging markets to advance wellness, prevention, treatments, and cures that challenge the most feared diseases of our time. Pfizer collaborates with healthcare providers, governments, and local communities to support and expand access to reliable, affordable healthcare around the world. Pfizer was incorporated under the laws of the State of Delaware on June 2, 1942.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 38 and therefore denies them.

39. Research and development ("R&D") is at the heart of fulfilling Pfizer's purpose to deliver breakthroughs that change patients' lives as Pfizer works to translate advanced science and technologies into the therapies that may be the most impactful for patients. The discovery and development of drugs, vaccines, and biological products are time consuming, costly, and unpredictable.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 39 and therefore denies them.

40. In December 2019, reports began circulating about an outbreak of pneumonia resulting in severe illness and death among people who were linked to the Huanan Seafood Wholesale Market in Wuhan, China.

ANSWER: CureVac admits the allegations in Paragraph 40.

The Development of COMIRNATY® Vaccine

41. By January 2020, it was discovered that the cause of this pneumonia outbreak was a novel coronavirus, eventually designated by the World Health Organization ("WHO") as SARS-CoV-2 with the disease it causes reclassified as Coronavirus disease 2019 ("COVID-19").

ANSWER: CureVac admits the allegations in Paragraph 41.

42. On March 11, 2020, the WHO designated COVID-19 an international pandemic as the disease quickly spread worldwide and tore through immunologically naïve populations, threatening the collapse of the healthcare system and loss of life at scales not seen since the advent of modern medicine.

ANSWER: CureVac admits that on March 11, 2020, the WHO designated COVID-19 an international pandemic. CureVac denies the remaining allegations in Paragraph 42.

43. In response, countries around the world instituted society-shaking restrictions on movement, requiring people to temporarily stay confined and isolated to their homes in an attempt to slow transmission of disease, save lives, and gain time to develop a fulsome response.

ANSWER: CureVac admits countries instituted certain restrictions in response to the spread of the virus that causes COVID-19. CureVac denies the remaining allegations in Paragraph 43.

44. To date, COVID-19 has infected at least 508 million people around the world, resulting in more than 6 million deaths. (Exhibit 4.)

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 44 and therefore denies them.

45. In the midst of the COVID-19 pandemic, many saw the development of highly effective and safe vaccines that successfully targeted and neutralized COVID-19 as the path out of the pandemic without a continuing, massive loss of life.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 45 and therefore denies them.

46. By early January of 2020, BioNTech initiated "Project Lightspeed," an accelerated vaccine development program to fight COVID-19. BioNTech's COVID-19 vaccine development program leveraged BioNTech's experience and expertise with mRNA technologies. For example, BioNTech has developed innovative, proprietary mRNA-based technologies to achieve effective translational performance and direction of the immune response.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 46 and therefore denies them.

47. BioNTech rapidly developed and performed numerous toxicological and pharmacological studies to determine the safety and efficacy of the COVID-19 vaccine. For example, BioNTech's studies showed, *inter alia*, that its COVID-19 vaccine is highly immunogenic in animal models and provided the needed confirmation to quickly move into Phase 1 clinical studies.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 47 and therefore denies them.

48. BioNTech and Pfizer decided to partner together on the development, clinical testing, manufacturing, distribution, and regulatory approval of the Pfizer-BioNTech COVID-19 vaccine. (Exhibit 6.)

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 48 and therefore denies them.

49. BioNTech and Pfizer agreed to share the costs of developing the COVID-19 vaccine. By the end of the first quarter of 2020, Pfizer had increased its yearly R&D budget by $500 million to reflect investments in combatting COVID-19. (Exhibit 7.)

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 49 and therefore denies them.

50. On May 5, 2020, BioNTech and Pfizer announced that the first participants had been dosed in the United States in the Phase 1/2 clinical trial for the BNT162 vaccine program to prevent COVID-19. (Exhibit 9.) After attaining promising Phase 1 clinical study results, BioNTech and Pfizer rapidly moved the Pfizer-BioNTech COVID-19 vaccine into the pivotal Phase 2 and studies—on a global scale encompassing more than 44,000 patients—to determine its safety and efficacy in humans

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 50 and therefore denies them.

51. Meanwhile, Pfizer was also working on the logistics and infrastructure needed to successfully manufacture and distribute the Pfizer-BioNTech COVID-19 vaccine. Pfizer activated its extensive manufacturing network and invested at risk in an effort to produce an approved COVID-19 vaccine as quickly as possible for those most in need around the world. Pfizer-owned sites in three U.S. states (Massachusetts, Michigan, and Missouri) and Puurs, Belgium were identified as manufacturing centers for COVID-19 vaccine production, with more sites to be selected. (Exhibit 10.)

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 51 and therefore denies them.

52. On July 13, 2020, BioNTech SE and Pfizer announced that investigational vaccine candidates from their BNT162 mRNA-based vaccine program being developed to help protect against SARS-CoV-2 (the virus that causes COVID-19) received Fast Track designation from the U.S. Food and Drug Administration ("FDA"). (Exhibit 11.)

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 52 and therefore denies them.

53. On July 27, 2020, BioNTech and Pfizer began a Phase 2/3 clinical study of their advanced nucleoside-modified messenger RNA candidate BNT162b2. (Exhibit 12.)

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 53 and therefore denies them.

54. In about November of 2020, the Pfizer-BioNTech COVID-19 vaccine was shown to have met all the primary efficacy endpoints in a Phase 3 clinical trial, demonstrating an efficacy rate of 95% ($p < 0.0001$) in participants without prior SARS-CoV-2 infection (first primary objective) and in participants with and without prior SARS-CoV-2 infection (second primary objective), as measured from seven days after the second dose of the vaccine. (Exhibit 13.)

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 54 and therefore denies them.

55. On November 20, 2020, Pfizer, on behalf of itself and BioNTech, submitted clinical trial data as part of an Emergency Use Authorization ("EUA") request to the FDA for administering the Pfizer-BioNTech COVID-19 vaccine to people 16 years of age and older.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 55 and therefore denies them.

56. On December 11, 2020, the FDA granted an EUA for the Pfizer-BioNTech COVID-19 vaccine for use in individuals 16 years of age and older.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 56 and therefore denies them.

57. The Pfizer-BioNTech COVID-19 vaccine was the first mRNA drug product, and the first vaccine to target COVID-19, authorized for emergency use in the United States.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 57 and therefore denies them.

58. As part of the fastest development of a vaccine in history, doses of the Pfizer-BioNTech COVID-19 vaccine were distributed immediately after the FDA granted an EUA.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 58 and therefore denies them.

59. On May 11, 2021, the FDA expanded the EUA for the Pfizer-BioNTech COVID-19 vaccine to include children as young as 12 years of age.

ANSWER: CureVac admits the allegations in Paragraph 59.

60. On October 29, 2021, the FDA also expanded the EUA for the Pfizer-BioNTech COVID-19 vaccine to include children as young as 5 years of age.

ANSWER: CureVac admits the allegations in Paragraph 60.

61. On June 17, 2022, the FDA further expanded the EUA for the Pfizer-BioNTech COVID-19 vaccine to include children as young as 6 months of age.

ANSWER: CureVac admits the allegations in Paragraph 61.

62. Based on a comprehensive data package and real-world results demonstrating the overwhelming safety and efficacy of the Pfizer-BioNTech COVID-19 vaccine, on August 23, 2021, the FDA granted full approval of the Pfizer-BioNTech COVID-19 vaccine for individuals 16 years of age and older.

ANSWER: CureVac admits that on August 23, 2021, BioNTech received approval to market Comirnaty® (tozinameran) in the United States. CureVac denies the remaining allegations in Paragraph 62.

63. In 2021, Pfizer manufactured more than three billion doses of the Pfizer-BioNTech COVID-19 vaccine. (Exhibit 14.) BioNTech and Pfizer expect to manufacture up to four billion doses in total by the end of 2022. *Id*.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 63 and therefore denies them.

64. The Pfizer-BioNTech COVID-19 vaccine fully approved by the FDA is marketed under the trade name COMIRNATY®.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 64 and therefore denies them.

65. COMIRNATY® vaccine was the first mRNA drug product, and the first COVID-19 vaccine to receive full FDA approval.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 65 and therefore denies them.

66. COMIRNATY® vaccine is indicated for "active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)." (Exhibit 15.)

ANSWER: CureVac admits that the quoted language appears in Exhibit 15 to the Complaint. CureVac lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 66 and therefore denies them.

67. Since receiving the first EUA from the FDA, COMIRNATY® vaccine has contributed to saving at least 14 million lives that otherwise may have been lost due to the pandemic. (Exhibit 16.) Furthermore, widespread vaccination of populations with COMIRNATY® vaccine allowed Massachusetts and other jurisdictions to remove restrictions on movement, easing the burdens countless individuals suffered during forced isolation.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 67 and therefore denies them.

68. Upon information and belief, CureVac was founded in 2000 and holds itself out to be a clinical stage biotechnology company.

ANSWER: CureVac admits that it was founded in 2000 and was the first company in the world to harness mRNA for medical purposes.

CureVac

69. Upon information and belief, CureVac had undertaken efforts aimed at developing at least one COVID-19 vaccine.

ANSWER: CureVac admits the allegations in Paragraph 69.

70. Upon information and belief, on or about June 16, 2021, a pivotal Phase 2b/3 clinical trial showed that CureVac's COVID-19 vaccine candidate, "CVnCoV," had an interim vaccine efficacy of only about 47% against COVID-19 of any severity and did not meet the pre-specified statistical success criteria. (Exhibit 4.)

ANSWER: CureVac admits that Exhibit 4 to the Complaint states (at page 146):

> Primary data was published in The Lancet on November 23, 2021. Overall, CVnCoV demonstrated a vaccine efficacy of 48% against COVID-19 disease of any severity. In the highly dynamic variant environment, the HERALD trial met the prespecified success criteria for efficacy against symptomatic COVID-19 of any severity and for efficacy against moderate-to-severe COVID-19, as defined in the protocol.

CureVac denies the remaining allegations in Paragraph 70.

71. Upon information and belief, in the day following the publication of the unsuccessful Phase 2b/3 clinical trial data of CVnCoV, the price of CureVac N.V.'s stock, which is publicly traded in the United States, fell by about 50%. (Exhibit 17.)

ANSWER: CureVac admits that Exhibit 17 to the Complaint states "The study data was released after the U.S. close Wednesday, and the shares dropped 44% in U.S. pre-market trading Thursday to below the price of the company's initial public offering last August."

CureVac denies the remaining allegations in Paragraph 71.

72. Upon information and belief, in about October of 2021, based on the disappointing results of its clinical studies, CureVac withdrew its CVnCoV vaccine candidate from the approval process with the European Medicines Agency. (Exhibit 18.)

ANSWER: CureVac admits that on October 12, 2021, CureVac N.V. issued the following statement:

> CureVac N.V. (Nasdaq: CVAC), a global biopharmaceutical company developing a new class of transformative medicines based on messenger ribonucleic acid ("mRNA"), today announced the strategic decision to focus its COVID-19 vaccine development towards the development of second-generation mRNA vaccine candidates in collaboration with GSK and to withdraw its first-generation COVID-19 vaccine candidate, CVnCoV, from the current approval process with the European Medicines Agency (EMA). In view of a recent EMA communication, CureVac estimates that the earliest potential approval of CVnCoV would come in the second quarter of 2022. By this time, the companies expect the candidates from the second-generation vaccine program to have progressed to late-stage clinical development. The decision is also aligned with the evolving dynamics of the

pandemic response towards a greater need for differentiated vaccines to address the developing endemic SARS-CoV2 situation.

CureVac denies the remaining allegations in Paragraph 72.

73. Upon information and belief, CureVac N.V.'s consolidated net losses for the years ending December 31, 2021 and December 31, 2020 were approximately €411.7 million and €129.1 million, respectively. As of December 31, 2021, CureVac N.V.'s accumulated deficit was approximately €1.06 billion. (Exhibit 4.)

ANSWER: CureVac admits that Exhibit 4 to the Complaint states (at 7):

> Our consolidated net loss for the years ended December 31, 2021 and 2020 were €411.7 million and €129.1 million, respectively. As of December 31, 2021, our accumulated deficit was €1,056.8 million. We expect to continue to incur losses in the future as we continue our research and development of, and seek regulatory approvals for, our product candidates and maintain and develop new technology platforms, prepare for and begin to commercialize any approved product candidates and add infrastructure and personnel to support our product development efforts and operations as a public company in the United States. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials and development of our manufacturing technology.

CureVac denies the remaining allegations in Paragraph 73.

74. Upon information and belief, in January 2022, CureVac N.V.'s Chief Technology Officer resigned from the company. (Exhibit 5.)

ANSWER: CureVac admits that CureVac N.V.'s Chief Technology Officer, Dr. Mariola Fotin-Mleczek, resigned from CureVac effective January 31, 2022.

75. Upon information and belief, CureVac N.V. has reported an expectation of continued losses in the future. (Exhibit 4.)

ANSWER: CureVac admits that Exhibit 4 to the Complaint states (at 7):

> We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability. We have incurred significant losses since our inception. Our consolidated net loss for the years ended December 31, 2021 and 2020 were €411.7 million and €129.1 million, respectively. As of December 31, 2021, our accumulated deficit was €1,056.8 million. We expect to continue to incur losses in the future as we continue our research and development of, and seek regulatory approvals for, our product candidates and maintain and develop new technology platforms, prepare for and begin to commercialize any approved product candidates and add infrastructure and

> personnel to support our product development efforts and operations as a public company in the United States. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials and development of our manufacturing technology.

CureVac denies the remaining allegations in Paragraph 75.

76. Upon information and belief, CureVac has reported that it has no history of commercializing pharmaceutical products, including any COVID-19 vaccine. (Exhibit 4.)

ANSWER: CureVac admits that Exhibit 4 to the Complaint states (at 5 and 11, respectively):

> We have no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.
>
> ****
>
> Our revenue to date has been primarily revenue from the license of our technology platform and from milestone payments for the development of product candidates against targets provided by our collaborators.

CureVac denies the remaining allegations in Paragraph 76.

77. Upon information and belief, CureVac has reported that it cannot give any assurance that any of its product candidates will receive regulatory approval in the future. (Exhibit 4.)

ANSWER: CureVac admits that Exhibit 4 to the Complaint states (at 4):

> Our proprietary product candidates are still in preclinical or clinical development. We cannot give any assurance that any of our product candidates will receive regulatory approval, and if we are unable to obtain regulatory approval and ultimately commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

CureVac denies the remaining allegations in Paragraph 77.

78. Upon information and belief, CureVac licensed from Acuitas Therapeutics, Inc. ("Acuitas") lipid nanoparticle ("LNP") technology developed by Acuitas.

ANSWER: CureVac admits that Exhibit 4 to the Complaint states (at 183):

> In April 2016, we entered into a Development and Option Agreement with Acuitas, which as amended we refer to as the Acuitas Agreement, pursuant to which Acuitas granted us the right to reserve a certain number of vaccine and other targets and an option to obtain a license to a certain number of such reserved targets to develop,

> manufacture and commercialize products containing Acuitas's LNP technology and mRNA constructs intended to express such targets. With respect to a certain number of non-exclusive licenses to vaccine targets that we obtain under the Acuitas Agreement, Acuitas additionally granted us an option to exchange each vaccine target licensed under such non-exclusive license for an alternate vaccine target for a certain period. As of December 31, 2021, we have exercised our option to obtain a non-exclusive license to 14 targets, and have not exercised our option to exchange a vaccine target licensed under any non-exclusive license. Under the Acuitas Agreement, Acuitas is responsible for the LNP chemistry and formulation and characterization work, and we are responsible for mRNA construct development.

CureVac denies the remaining allegations in Paragraph 78.

79. Upon information and belief, as of January 2020, CureVac was aware that BioNTech had licensed LNPs from Acuitas for use with mRNA therapeutic products.

ANSWER: CureVac denies the allegations in Paragraph 79.

80. Upon information and belief, CureVac used the LNP technology it licensed from Acuitas in its failed COVID-19 vaccine candidate.

ANSWER: CureVac admits that CureVac's first-generation COVID-19 vaccine candidate, CVnCoV, used LNP technology licensed from Acuitas. CureVac denies the remaining allegations in Paragraph 80.

81. In about February 2022, after CureVac had withdrawn its CVnCoV vaccine candidate from the regulatory approval process, CureVac N.V. contacted BioNTech SE, Pfizer's collaboration partner, seeking to initiate discussions between the IP counsel of CureVac and BioNTech SE regarding the potential licensing of certain IP rights from CureVac.

ANSWER: CureVac denies the allegations in Paragraph 81.

CureVac's Assertion of the Patents-in-Suit against BioNTech and Pfizer

82. Upon information and belief, CureVac N.V. had at that time a deadline to report financial results and provide business updates for the fourth quarter and full-year of 2021 on April 28, 2022.

ANSWER: CureVac admits that CureVac reported its fourth quarter and full year of 2021 financial results on April 28, 2022. CureVac denies the remaining allegations in Paragraph 82.

83. CureVac contacted the Senior Patent Counsel of BioNTech US Inc., which is located in Cambridge, Massachusetts, regarding the licensing of certain IP rights from CureVac in connection with COMIRNATY® vaccine. At that time, it was publicly known that BioNTech and Pfizer were collaborating on the manufacture of COMIRNATY® vaccine and that Pfizer manufactured COMIRNATY® vaccine in the United States.

ANSWER: CureVac denies the allegations in Paragraph 83.

84. Upon information and belief, at all relevant times since the initial contact described above, CureVac was aware that Pfizer manufactures and is responsible for the distribution and sale of COMIRNATY® vaccine in the United States, including in Massachusetts.

ANSWER: CureVac admits the allegations in Paragraph 84.

85. At all relevant times, BioNTech and Pfizer have worked together with respect to CureVac's accusations.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 85 and therefore denies them.

86. CureVac and BioNTech SE held a videoconference on April 4, 2022, and an in-person meeting on April 7, 2022.

ANSWER: CureVac admits the allegations in Paragraph 86.

87. On March 29, 2022, CureVac sent BioNTech SE a document identifying CureVac's purported IP portfolio. This document included the patents-in-suit and related patents, of which the patents-in-suit are representative family members.

ANSWER: CureVac admits that on March 29, 2022, CureVac sent employees of BioNTech an electronic copy of a presentation. CureVac denies the remaining allegations in Paragraph 87.

88. On June 9, 2022, CureVac and BioNTech SE conducted a meeting relating to CureVac's threat to assert its patents in connection with COMIRNATY® vaccine. Such threat included both United States patents and their European counterparts.

ANSWER: CureVac admits that on June 9, 2022, employees of CureVac and BioNTech SE communicated by a videoconference. CureVac denies the remaining allegations in Paragraph 87.

89. Upon information and belief, CureVac was aware that BioNTech SE was acting in the discussions with the knowledge of both BioNTech and Pfizer.

ANSWER: CureVac cannot understand the allegations in Paragraph 89. To the extent the allegations are intelligible, CureVac denies the allegations in Paragraph 89.

90. The parties did not reach an amicable resolution of CureVac's threats. CureVac has stated that the parties' "out-of-court dispute resolution efforts have not been successful." (Exhibit 19.)

ANSWER: CureVac admits that Exhibit 19 to the Complaint contains the statement "out-of-court dispute resolution efforts have not been successful." CureVac denies the remaining allegations in Paragraph 90.

91. Upon information and belief, individuals from CureVac who were involved in the communications regarding CureVac's IP rights in connection with COMIRNATY® vaccine included the Chief Business Officer and Chief Commercial Officer of CureVac, the Vice President, Patents of CureVac, the Head of IP Management of CureVac, and the Director IP Management US of CureVac, Inc.

ANSWER: CureVac admits CureVac's Chief Business Officer, Chief Commercial Officer, Vice President, Patents, Head of IP Management of CureVac, and the Director IP Management US of CureVac, Inc. engaged in communications with BioNTech regarding CureVac's IP rights. CureVac denies the remaining allegations in Paragraph 91.

92. On June 29, 2022, following the failed dispute resolution efforts, CureVac submitted an infringement complaint to the German Regional Court in Düsseldorf against BioNTech SE, BioNTech Manufacturing GmbH, and BioNTech Manufacturing Marburg GmbH, alleging, *inter alia*, that the manufacture and sale of COMIRNATY® vaccine infringes European counterparts to the patents-in-suit. (Exhibit 19.)

ANSWER: CureVac admits that on June 29, 2022, CureVac N.V. filed a lawsuit in the German Regional Court in Düsseldorf against BioNTech SE and two of its subsidiaries, seeking fair compensation for infringement of European and German patents EP 1 857 122 B1, DE 20 2015 009 961 U1, DE 20 2021 003 575 U1 and DE 20 2015 009 974 U1. CureVac denies the remaining allegations in Paragraph 92.

93. On July 5, 2022, CureVac N.V. issued a press release announcing that "it has moved to assert its intellectual property rights" against BioNTech. (Exhibit 20.)

ANSWER: CureVac admits that on July 5, 2022, CureVac N.V. issued a press release (Exhibit 20 to the Complaint) which stated:

> [CureVac N.V.] has moved to assert its intellectual property rights, accumulated over more than two decades of pioneering work in mRNA technology, which contributed to COVID-19 vaccine development. CureVac has filed a lawsuit in the German Regional Court in Düsseldorf against BioNTech SE and two of its subsidiaries, seeking fair compensation for infringement of a portfolio of CureVac's intellectual property rights, EP 1 857 122 B1, DE 20 2015 009 961 U1, DE 20 2021 003 575 U1 and DE 20 2015 009 974 U1, utilized in the manufacture and sale of Comirnaty®, BioNTech and Pfizer's mRNA COVID-19 vaccine. CureVac does not seek an injunction nor intend to take legal action that impedes the production, sale or distribution of Comirnaty® by BioNTech and its partner Pfizer.
>
> The CureVac intellectual property portfolio protects multiple inventions that are considered essential to the design and development of BioNTech's SARS CoV-2 mRNA vaccine, among others. These relate to the engineering of mRNA molecules, including sequence modifications to increase stability and enhance protein expression, as well as mRNA vaccine formulations specific to SARS CoV-2 vaccines.
>
> Over the last 22 years, CureVac developed proprietary foundational technology related to mRNA design, delivery and manufacturing that materially contributed to the development of safe and efficacious COVID-19 vaccines. CureVac considers the rapid development of these vaccines a tremendous achievement, with unprecedented positive impact for global public health. This achievement is based on decades of scientific research and innovation, supported by CureVac as the earliest pioneer in mRNA technology. Accordingly, CureVac's intellectual property rights need to be acknowledged and respected in the form of a fair compensation to reinvest into the further advancement of mRNA technology and the ongoing development of new classes of life saving medicines.

94. That same day, following CureVac's announcement of its lawsuit against BioNTech and that it intended to assert its intellectual property rights against COMIRNATY® vaccine, news reports indicated that Pfizer's stock fell over 3.5%. (Exhibit 21.)

ANSWER: CureVac admits that Exhibit 21 to the Complaint states:

> Shares in CureVac fell 2% by midday, having previously jumped almost 5% in premarket trading following news of the lawsuit. BioNTech stock slipped 0.5% and shares in Pfizer lost 3.5%.

CureVac denies the remaining allegations in Paragraph 94.

95. The German infringement complaint does not name Pfizer. Pfizer does not manufacture or sell COMIRNATY® vaccine in Germany. According to news reports, however, when asked in a media call, CureVac's chief executive said that he was not ruling out further legal action against BioNTech partner Pfizer. (Exhibit 22.)

ANSWER: CureVac admits that the German infringement complaint names BioNTech SE, BioNTech Manufacturing GmbH, and BioNTech Manufacturing Marburg GmbH, and that Exhibit 22 to the Complaint states:

> When asked in a media call, [CureVac N.V.] Chief Executive Franz-Werner Haas did not rule out further legal action against BioNTech partner Pfizer (PFE.N) or mRNA vaccine maker CureVac (MRNA.O)"; that Dr. Haas also said "Many years of our research have also contributed to the success of the mRNA vaccines and made that possible, . . . From our point of view, it is self-evident to respect the associated property rights"; and that "CureVac said that its claim to intellectual property rights was based on more than two decades of work on mRNA technology, some of which was used by BioNTech and Pfizer for the development and sale of their Comirnaty coronavirus vaccine." CureVac is without information sufficient to form a belief as to the other allegations in this paragraph, and on that basis, denies them. Based on, at a minimum, CureVac's assertion of the patents-in-suit and commencement of litigation with respect to European counterparts of such patents in connection with COMIRNATY® vaccine, an actual, immediate, substantial, and justiciable controversy exists between BioNTech, Pfizer, and CureVac as to whether COMIRNATY® vaccine has infringed or will infringe the patents-in-suit.

CureVac denies the remaining allegations in Paragraph 95.

96. Based on, at a minimum, CureVac's assertion of the patents-in-suit and commencement of litigation with respect to European counterparts of such patents in connection with COMIRNATY® vaccine, an actual, immediate, substantial, and justiciable controversy exists between BioNTech, Pfizer, and CureVac as to whether COMIRNATY® vaccine has infringed or will infringe the patents-in-suit.

ANSWER: Insofar as Paragraph 96 contains legal conclusions, no response is required. To the extent that a response is required, CureVac denies the allegations in Paragraph 96.

97. Plaintiffs fund pharmaceutical research and development in part with revenues from COMIRNATY® vaccine. CureVac's assertion of the patents-in-suit in connection with COMIRNATY® vaccine has created a cloud of uncertainty, *inter alia*, with respect to what

portion of the revenues from COMIRNATY® vaccine Plaintiffs may invest into that research and development.

ANSWER: CureVac lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 97 and therefore denies them.

THE PATENTS-IN-SUIT

U.S. Patent No. 11,135,312 ("the '312 patent")

98. Upon information and belief, the '312 patent, titled "Pharmaceutical Composition Containing a Stabilised mRNA Optimised for Translation in its Coding Regions," issued on October 5, 2021. The '312 patent names Florian Von Der Mülbe, Ingmar Hoerr, and Steve Pascolo as inventors. Upon information and belief, CureVac appears to be the assignee of the '312 patent. A true and correct copy of the '312 patent is attached to this Complaint as Exhibit 1.

ANSWER: CureVac admits that the allegations in Paragraph 98.

99. The '312 patent contains an independent claim 1 that recites a "method for producing a stabilized mRNA molecule encoding a polypeptide, wherein the stabilized mRNA molecule encoding the polypeptide comprises a coding sequence that has an increased Guanine/Cytosine (G/C) content relative to the original coding sequence encoding the polypeptide, said relative G/C content being increased by at least 7 percentage points compared to the original coding sequence encoding the polypeptide, to thereby produce a stabilized mRNA molecule, wherein said increase in relative G/C content results in the elimination of at least one destabilizing sequence element (DSE), wherein the stabilized mRNA molecule Exhibits enhanced expression of the polypeptide compared to mRNA having the original coding sequence encoding the polypeptide."

ANSWER: CureVac admits that the allegations in Paragraph 99.

U.S. Patent No. 11,149,278 ("the '278 patent")

100. Upon information and belief, the '278 patent, titled "Artificial Nucleic Acid Molecules for Improved Protein Expression," issued on October 19, 2021. The '278 patent names Andreas Thess, Thomas Schlake, and Stefanie Grund as inventors. Upon information and belief, CureVac appears to be the assignee of the '278 patent. A true and correct copy of the '278 patent is attached to this Complaint as Exhibit 2.

ANSWER: CureVac admits that the allegations in Paragraph 100.

101. The '278 patent contains an independent claim 1 that recites a "method for treating or preventing an infectious disease, the method comprising administering an RNA molecule comprising: a) at least one open reading frame (ORF) encoding an antigen from a pathogen associated with the infectious disease; and b) a 3'-untranslated region (3'-UTR) comprising at least two poly(A) sequences, wherein at least one of the poly(A) sequences

comprises at least 70 adenine nucleotides, wherein the at least two poly(A) sequence elements are separated by a nucleic acid sequence comprising from 10 to 90 nucleotides, wherein the RNA molecule is administered intramuscularly."

ANSWER: CureVac admits that the allegations in Paragraph 101.

U.S. Patent No. 11,241,493 ("the '493 patent")

102. Upon information and belief, the '493 patent, titled "Coronavirus Vaccine," issued on February 8, 2022. The '493 patent names Susanne Rauch, Hans Wolfgang Große, and Benjamin Petsch as inventors. Upon information and belief, CureVac appears to be the assignee of the '493 patent. A true and correct copy of the '493 patent is attached to this Complaint as Exhibit 3.

ANSWER: CureVac admits that the allegations in Paragraph 102.

103. The '493 patent contains an independent claim 1 that recites a "composition comprising a mRNA comprising," *inter alia,* "at least one coding sequence encoding a SARS-CoV-2 spike protein (S)" and "at least one pharmaceutically acceptable carrier, wherein the mRNA is complexed or associated with lipid nanoparticles." Claim 1 also recites that "the LNP comprises" "at least one cationic lipid according to formula III-3," "at least one neutral lipid, comprising 1,2-distearoylsn-glycero-3-phosphocholine (DSPC)," "at least one steroid, comprising cholesterol," and "at least one PEG-lipid according to formula IVa." Claim 1 further recites that the lipids comprising the LNP "are in a molar ratio of about 20-60% cationic lipid, 5-25% neutral lipid, 25-55% sterol, and 0.5-15% PEG-lipid."

ANSWER: CureVac admits that the allegations in Paragraph 103.

COUNT I: NONINFRINGEMENT OF THE '312 PATENT

104. Plaintiffs incorporate by reference herein all of the allegations of paragraphs 5 to 103.

ANSWER: CureVac repeats and incorporates by references its responses to paragraphs 5 to 103 of the Complaint.

105. There is an actual case or controversy between Plaintiffs and CureVac as to whether COMIRNATY® vaccine is manufactured by a method that meets all of the limitations of any claim of the '312 patent and whether the manufacture, use, offer to sell, and sale of COMIRNATY® vaccine, and the importation of COMIRNATY® vaccine into the United States, infringes any claim of the '312 patent.

ANSWER: CureVac admits that the allegations in Paragraph 105.

106. The manufacture, use, offer to sell, and sale of COMIRNATY® vaccine, and the importation of COMIRNATY® vaccine into the United States, does not infringe any claim of the '312 patent.

ANSWER: CureVac denies the allegations in Paragraph 106.

107. For example, COMIRNATY® vaccine is not manufactured by a method that comprises "synthesizing a stabilized mRNA molecule encoding a polypeptide, wherein the stabilized mRNA molecule encoding the polypeptide comprises a coding sequence that has an increased Guanine/Cytosine (G/C) content relative to the original coding sequence encoding the polypeptide," as required by all of the claims of the '312 patent to the extent understood.

ANSWER: CureVac denies the allegations in Paragraph 107.

108. Plaintiffs are entitled to a judgment that COMIRNATY® vaccine is not manufactured by a method that meets all of the limitations of any claim of the '312 patent and that the manufacture, use, offer to sell, and sale of COMIRNATY® vaccine, and the importation of COMIRNATY® vaccine into the United States, does not infringe any claim of the '312 patent.

ANSWER: CureVac denies the allegations in Paragraph 108.

COUNT II: NONINFRINGEMENT OF THE '278 PATENT

109. Plaintiffs incorporate by reference herein all of the allegations of paragraphs 5 to 108.

ANSWER: CureVac repeats and incorporates by references its responses to paragraphs 5 to 108 of the Complaint.

110. There is an actual case or controversy between Plaintiffs and CureVac as to whether COMIRNATY® vaccine meets all the limitations of any claim of the '278 patent and whether the manufacture, use, offer to sell, and sale of COMIRNATY® vaccine, and the importation of COMIRNATY® vaccine into the United States, infringes any claim of the '278 patent.

ANSWER: CureVac admits the allegations in Paragraph 110.

111. The manufacture, use, offer to sell, and sale of COMIRNATY® vaccine, and the importation of COMIRNATY® vaccine into the United States, does not infringe any claim of the '278 patent.

ANSWER: CureVac denies the allegations in Paragraph 111.

112. For example, COMIRNATY® vaccine does not comprise "a 3'-untranslated region (3'-UTR) comprising at least two poly(A) sequences," as required by all of the claims of the '278 patent to the extent understood.

ANSWER: CureVac denies the allegations in Paragraph 112.

113. Plaintiffs are entitled to a judgment that COMIRNATY® vaccine does not meet all of the limitations of any claim of the '278 patent and that the manufacture, use, offer to sell, and sale of COMIRNATY® vaccine, and the importation of COMIRNATY® vaccine into the United States, does not infringe any claim of the '278 patent.

ANSWER: CureVac denies the allegations in Paragraph 113.

COUNT III: NONINFRINGEMENT OF THE '493 PATENT

114. Plaintiffs incorporate by reference herein all of the allegations of paragraphs 5 to 113.

ANSWER: CureVac repeats and incorporates by references its responses to paragraphs 5 to 113 of the Complaint.

115. There is an actual case or controversy between Plaintiffs and CureVac as to whether COMIRNATY® vaccine meets all the limitations of any claim of the '493 patent and whether the manufacture, use, offer to sell, and sale of COMIRNATY® vaccine, and the importation of COMIRNATY® vaccine into the United States, infringes any claim of the '493 patent.

ANSWER: CureVac admits the allegations in Paragraph 115.

116. The manufacture, use, offer to sell, and sale of COMIRNATY® vaccine, and the importation of COMIRNATY® vaccine into the United States, does not infringe any claim of the '493 patent.

ANSWER: CureVac denies the allegations in Paragraph 116.

117. For example, COMIRNATY® vaccine does not comprise a "composition comprising a mRNA comprising . . . at least one pharmaceutically acceptable carrier, wherein the mRNA is complexed or associated with lipid nanoparticles," as required by all of the claims of the '493 patent to the extent understood.

ANSWER: CureVac denies the allegations in Paragraph 117.

118. Plaintiffs are entitled to a judgment that COMIRNATY® vaccine does not meet all of the limitations of any claim of the '493 patent and that the manufacture, use, offer to sell, and sale of COMIRNATY® vaccine, and the importation of COMIRNATY® vaccine into the United States, does not infringe any claim of the '493 patent.

ANSWER: CureVac denies the allegations in Paragraph 118.

AFFIRMATIVE AND OTHER DEFENSES

1. The Complaint fails to state a claim upon which relief may be granted.

2. CureVac is entitled to judgment as a matter of law on the allegations in the Complaint.

PRAYER FOR RELIEF

The Complaint recites a prayer for relief to which no response is required. To the extent a response is required, CureVac denies that Plaintiffs are entitled to any remedy or relief.

Dated: May 19, 2023

/s/ *John M. Erbach*

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